

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

_____	x	
	:	
THE CITY OF HUNTINGTON,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01362
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

_____	x	
	:	
CABELL COUNTY COMMISSION,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01665
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

BENCH TRIAL - VOLUME 22
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JUNE 8, 2021

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Proceedings recorded by mechanical stenography;
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1 PROCEEDINGS had before The Honorable David A.
2 Faber, Senior Status Judge, United States District
3 Court, Southern District of West Virginia, in
4 Charleston, West Virginia, on June 8, 2021, at 9:00
5 a.m., as follows:

6 THE COURT: Ms. Singer?

7 MS. SINGER: Good morning, Your Honor. Shall we
8 call the witness back to the stand?

9 THE COURT: Okay.

10 Resume the witness stand, Mr. Rannazzisi. Good
11 morning, sir.

12 THE WITNESS: Good morning, sir.

13 THE COURT: You're still under oath.

14 THE WITNESS: Thank you.

15 BY MS. SINGER:

16 **Q.** All right. Good morning, Mr. Rannazzisi. Yesterday I
17 promised we would start with a road map or follow a road
18 map. Today, we may go a little off road. So, please bear
19 with me.

20 So, I want to pick up where we were after the
21 distributor initiative briefings that you testified about
22 yesterday. Now, after the DEA met with each of the
23 defendants in 2005, did you and your staff check to see
24 whether the meetings had had any impact?

25 **A.** Yes, we did.

1 **Q.** And what did you do?

2 **A.** After a brief period of time, we --

3 MR. WESTFALL: Your Honor --

4 THE WITNESS: -- requested an ARCOS review for
5 sales.

6 MR. WESTFALL: Your Honor, in terms of his
7 testimony, again, he can disclose anything that's not
8 privileged, any public information, but anything that he
9 discussed and --

10 COURT REPORTER: I can't hear you, Mr. Westfall.
11 I'm sorry.

12 MR. WESTFALL: He can disclose any public
13 information or any non-privilege information, but any answer
14 that he gives that would be based upon attorney-client
15 communications, deliberative process privilege or would
16 reveal law enforcement sensitive techniques, he's been
17 instructed not to answer. That's what I wanted to indicate
18 on the record.

19 THE COURT: Well, we understand all that.

20 MR. WESTFALL: Thank you, Your Honor.

21 THE COURT: The only way I can handle it is deal
22 with specific questions as they come up, Mr. Westfall. So,
23 if you have any problem with any of Ms. Singer's questions,
24 you can interject.

25 MR. WESTFALL: Thank you, Your Honor.

1 THE COURT: Otherwise, we'll press on.

2 BY MS. SINGER:

3 Q. All right. So, Mr. Rannazzisi, what did you do?

4 A. I asked for an ARCOS review in December to determine
5 what happened to the flow to specific pharmacies downstream
6 from specific wholesalers.

7 Q. And when you say December, do you mean -- what year do
8 you mean?

9 A. December of 2005.

10 Q. Okay. And what did you find when you -- when you
11 undertook that review?

12 A. They continued -- one particular defendant continued to
13 distribute large volumes of controlled substances
14 downstream.

15 Q. And which defendant was that?

16 A. McKesson.

17 Q. And so, what did you do?

18 A. I asked them to come in for a meeting.

19 Q. And did that meeting take place?

20 A. Yes.

21 Q. And what happened? Well, first of all, when was that
22 meeting; do you recall?

23 A. That would have been probably January 3rd. January 3rd
24 or January 4th of 2006.

25 Q. Right after the new year, yes?

1 **A.** Yes.

2 **Q.** All right.

3 MS. SINGER: Can we have P-09116, please?

4 Your Honor, may I approach?

5 THE COURT: Yes.

6 BY MS. SINGER:

7 **Q.** All right. Mr. Rannazzisi, do you recognize this
8 document?

9 **A.** Yes, ma'am.

10 **Q.** And what do you recognize it to be?

11 **A.** This is basically the results of the meeting, the
12 written results of the meeting.

13 **Q.** And by "the meeting", you mean the meeting between DEA
14 and McKesson?

15 **A.** Yes, ma'am.

16 **Q.** Okay.

17 MS. SINGER: All right. And let me just ask, are
18 you -- can you hear him? Is he speaking loud enough?

19 COURT REPORTER: Yes. Thank you.

20 MS. SINGER: Okay.

21 BY MS. SINGER:

22 **Q.** All right. Now, who was this memo to?

23 **A.** Joseph Rannazzisi, me.

24 **Q.** And who was it from?

25 **A.** Michael Mapes.

1 Q. Okay. And I think you mentioned Mr. Mapes yesterday,
2 but who is he?

3 A. Michael Mapes was the Section Chief for E-commerce.

4 Q. And what was the purpose of this memo?

5 A. To document exactly what happened during the meeting.

6 Q. And were you at the meeting?

7 A. Yes, I was.

8 Q. And do you know whether this memo accurately reflects
9 what happened at that meeting?

10 A. Yes, it does.

11 MS. SINGER: Your Honor, I would move to admit
12 P-09116.

13 THE COURT: Mr. Schmidt?

14 MR. SCHMIDT: We maintain our geographic scope
15 objection. The document is clear on its face. It relates
16 to pharmacies in the Tampa, Florida area.

17 THE COURT: Well, I'm going to overrule that
18 objection for the reasons I overruled the similar objection
19 yesterday during Mr. Rannazzisi's testimony. I think it --
20 it embraces the entire situation here with regard to
21 McKesson, which would include the geographic area issue
22 here. So, to that extent, it goes to the weight rather than
23 the admissibility and your objection is overruled.

24 MR. SCHMIDT: May I just preserve that on a
25 running basis, Your Honor?

1 THE COURT: Absolutely.

2 MR. SCHMIDT: Thank you.

3 BY MS. SINGER:

4 Q. Mr. Rannazzisi, where was the meeting with McKesson
5 held?

6 A. At the DEA Headquarters.

7 Q. And do you recall who was there for McKesson?

8 A. It was their senior leadership.

9 Q. And how did the meeting open?

10 A. We started to discuss the transactions. Mike Mapes
11 discussed the meeting. The -- actually, Mike Mapes started
12 by discussing the initial meeting.

13 MR. SCHMIDT: This is literally hearsay, Your
14 Honor.

15 THE COURT: I will sustain the objection to the
16 hearsay.

17 MS. SINGER: Your Honor, I would say that this is
18 an account of the guidance that -- that the DEA provided to
19 McKesson and we would ask that it be -- that Mr.
20 Rannazzisi's testimony be allowed to go to notice to this
21 defendant about what the DEA was instructing them.

22 THE COURT: Well, you can question him about what
23 he knows about it, but what Mr. Mapes said, I think, is out
24 of bounds. It is hearsay.

25 BY MS. SINGER:

1 **Q.** All right. Mr. Rannazzisi, subject to that direction,
2 can you recount what you recall happened at that meeting?
3 What did DEA say to McKesson?

4 **A.** We presented --

5 MR. SCHMIDT: Same. Same objection, Your Honor.

6 THE COURT: Sustained. Just -- you can ask him
7 what his recollection is and what happened at the meeting,
8 but don't ask him what anybody said.

9 MS. SINGER: Okay.

10 BY MS. SINGER:

11 **Q.** Mr. Rannazzisi, I'm going to ask you the Court's
12 question, which is what happened at that meeting?

13 **A.** We presented information concerning ARCOS data that
14 showed that they were continuing to ship large volumes
15 downstream of hydrocodone to specific pharmacies that we
16 told them were showing patterns of suspicion, suspicious
17 orders, and we requested an answer why they were shipping,
18 continuing to ship these -- these huge quantities of
19 hydrocodone to these pharmacies after they were directed to
20 review the pharmacies' purchases and make a determination.

21 **Q.** And between the distributor initiative meeting and this
22 meeting with McKesson at DEA Headquarters on January 3rd,
23 had there been other communications with McKesson about
24 these issues?

25 **A.** I've got to -- could you please repeat the question?

1 **Q.** Yes. Let me actually direct you to the document that's
2 in evidence rather than repeat the question. Can you look
3 at the bullets at the bottom of the page, Mr. Rannazzisi,
4 the first page?

5 **A.** Yes.

6 **Q.** Okay. And does the memo recount that there were
7 communications between DEA and McKesson about its shipment
8 to these pharmacies between the distributor initiative and
9 the January 3rd meeting.

10 MR. SCHMIDT: Objection, Your Honor. Vague. I
11 think the fact is the earlier memo told us two pharmacies
12 were mentioned. Now we're up to six.

13 THE COURT: Well, overruled. If you can clear it
14 up, Ms. Singer, please.

15 THE WITNESS: Yes. At the -- at the initial
16 meeting two pharmacies were presented, yes, and they were
17 told that this is a -- this is a suspicious order. This is
18 what you're supposed to be looking for. These are the
19 quantities you're supposed to be looking for. This is --
20 these are the flags you're supposed to be looking for, the
21 red flags, black flags, whatever you want to call them.

22 MR. SCHMIDT: And, again, Your Honor, I'm going to
23 move to strike. He wasn't at that earlier meeting. If they
24 want to show him a document and have read him a document,
25 that's fine, but he's literally testifying about a meeting

1 he was not at and I don't believe that level of detail is
2 contained in the document we were sent.

3 MS. SINGER: I believe Mr. Rannazzisi is
4 testifying as to his recollection of what occurred.

5 THE COURT: Overruled. Overruled. I will let him
6 answer.

7 BY MS. SINGER:

8 Q. Mr. Rannazzisi, had you finished your answer?

9 A. Yes.

10 Q. Okay. And so, between the distributor initiative
11 meeting, does this memo recount additional communications
12 between DEA and McKesson?

13 A. May I have a second?

14 Q. Of course.

15 A. Yes, it does.

16 Q. And what were those communications?

17 A. Between DEA Section Chief and counsel for McKesson.

18 Q. And do you know how many communications there were?

19 A. At least one.

20 Q. Okay.

21 A. And then there was -- there was communication between a
22 DEA investigator in Tampa and the McKesson Distribution
23 Center at Lakeland.

24 Q. And let's turn to Page 2 of the memo, please.

25 A. Yes.

1 MS. SINGER: And can we pull up, Gina, the second
2 page at the top, please?

3 BY MS. SINGER:

4 Q. Mr. Rannazzisi, I direct you to the third bullet on the
5 second page of the memo. Can you read what it says there?

6 A. The E-commerce section retrieved ARCOS data which
7 revealed that between October 10th and October 21st, 2005,
8 the following alleged internet pharmacies received the
9 identified quantities of hydrocodone. So that's an 11-day
10 period.

11 Q. Okay. And where -- I see the names of the pharmacies
12 are redacted, but what is the number that follows each of
13 those names?

14 A. The 11-day period, first pharmacy was at 252,100 dosage
15 units of hydrocodone.

16 Q. And what's a dosage unit?

17 A. It could be a 5-milligram, 7-and-a-half-milligram, or a
18 10-milligram tablet.

19 Q. So, a dosage unit is a pill, correct?

20 A. Yes.

21 Q. Okay. And these volumes that you see in this memo, was
22 that an unusual volume of pills for McKesson to have
23 shipped?

24 A. For 11 days, absolutely.

25 Q. And so, did you ask McKesson for an explanation about

1 that volume of pills?

2 **A.** Yes, I did.

3 **Q.** And what did McKesson say?

4 **A.** They couldn't give me a reason.

5 **Q.** And can you recall precisely how McKesson responded to
6 your request for an explanation to the extent you recall?

7 **A.** When I went through the numbers, I asked them could you
8 give me any type of explanation about why you were shipping
9 these quantities of drugs and I stared at them and they
10 shuffled papers and looked around. And then a guy, one of
11 the gentlemen, kind of gave me a little smile and said,
12 "Well, I guess you got us."

13 **Q.** And so, what happened after that?

14 **A.** I was floored by that statement. You know, they said,
15 "We can't tell you why. We -- we don't know." And it -- it
16 upset me. It really upset me.

17 **Q.** And why did it upset you?

18 **A.** In 11 days, a pharmacy is getting --

19 MR. SCHMIDT: Objection, relevance. The fact that
20 he's upset is not a relevant fact in this case.

21 MS. SINGER: It goes to explain DEA's --

22 THE COURT: Yeah. I'll overrule the objection.
23 You can answer it.

24 THE WITNESS: In 11 days a pharmacy got 520,000
25 hydrocodone tablets. Doing the math, you know, that's what,

1 four -- that's just -- it's a crazy number. It would be
2 over 500 hydrocodone prescriptions a day. That's -- that's
3 insane. At 120 doses, that's insane. And -- and there's --
4 there's no legitimate reason to have that much.

5 BY MS. SINGER:

6 **Q.** And so, after McKesson responded, and I don't want to
7 re-state your words, but you considered that, what happened
8 after that?

9 **A.** Well, they called later and said that their system was
10 not picking up generic drugs in the hydrocodone basic class.

11 **Q.** And what do you mean their system?

12 **A.** Their -- the system to identify suspicious orders.

13 **Q.** Okay. And it was not picking up generic --

14 **A.** Hydrocodone products.

15 **Q.** Okay. And was that a surprising fact to you?

16 **A.** Yeah, because the -- the Suspicious Order Monitoring
17 Program is supposed to pick up all controlled substances, be
18 it generic or brand name.

19 **Q.** And was it a big issue in terms of McKesson's
20 compliance that its system was not monitoring generic drugs?

21 **A.** Yeah. It's a systemic failure. If one -- if one
22 facility was not picking that up, then chances are all the
23 facilities weren't picking it up because it was a nationwide
24 system.

25 MR. SCHMIDT: Objection. Object to foundation,

1 Your Honor. Pure speculation.

2 MS. WICHT: Your Honor, sorry. I would add to
3 that that I believe it's calling for a legal conclusion in
4 terms of system failure and whether it's compliant, which I
5 believe is how he phrased it.

6 MR. SCHMIDT: Yeah.

7 MS. SINGER: So, Your Honor --

8 THE COURT: I think it's -- I'll sustain the
9 objection. I think it's speculation on his part. I'll
10 sustain the objection. Go ahead and ask him the next
11 question.

12 BY MS. SINGER:

13 **Q.** Mr. Rannazzisi, did you have reason to know back in
14 2006, when you met with McKesson, whether McKesson operated
15 a single national compliance system?

16 **A.** At that point in time, yes. There was supposed to be.
17 I -- I -- at that point in time, I knew based on my
18 briefings that they were operating a single system, yes.

19 **Q.** And so, was -- was McKesson's failure to identify
20 generic or monitor generic drugs that it was shipping a
21 systemic failure?

22 MR. SCHMIDT: Same objection, Your Honor. The
23 fact that this happened at one location and the fact that he
24 knew he had a national policy, that doesn't bridge to the
25 opinion, the legal opinion they're trying to elicit from him

1 now, or give a factual basis for it.

2 MS. SINGER: Your Honor --

3 THE COURT: Well, I will overrule the objection,
4 if he knows. He can answer.

5 THE WITNESS: Could you repeat the question?

6 BY MS. SINGER:

7 Q. I'm asking whether you knew back in 2006 whether the
8 failure to monitor generic drugs was a systemic failure at
9 McKesson?

10 A. Based on what I knew of the system, yes.

11 Q. And do you have any doubt about that?

12 A. No.

13 Q. Now, yesterday, we talked about internet pharmacies and
14 we're not going to re-tread that ground except for a minute.
15 The internet pharmacies that DEA was focused on, where were
16 most of those pharmacies located?

17 A. Most of the internet pharmacies were located in
18 Florida. The brick and mortar pharmacies were located in
19 Florida.

20 Q. And can you explain briefly the relationship between an
21 internet pharmacy and a brick and mortar pharmacy?

22 A. Well, an internet pharmacy is not really a pharmacy.
23 It's a facilitation center in cyberspace. They take orders.
24 They give you questionnaires to fill out.

25 They -- they're like a traffic cop. They send those

1 questionnaires to a doctor. A doctor looks at the
2 questionnaire. He might call the patient, might not, but in
3 either case, whether he calls or not, he approves a
4 prescription, goes back to the facilitation center, and it
5 goes up on to a bulletin board where a pharmacy somewhere
6 pulls it down and fills it and ships it to a patient, to a
7 drug-seeking patient.

8 **Q.** And, to your knowledge, is there any interaction
9 between the doctor who is prescribing and the patient who is
10 receiving those prescriptions?

11 **A.** The cases that DEA did, for the most part, there was no
12 doctor-patient interaction. There may have been a phone
13 call. That's about it. But almost all the cases, it was
14 just a review of a questionnaire, sign -- approve the
15 prescription. Prescription gets sent to the facilitation
16 center, up onto the bulletin board where a pharmacy fills
17 the prescription.

18 **Q.** So, was there any kind of a physical examination of the
19 patient?

20 **A.** No.

21 **Q.** And over time did internet pharmacies give way to other
22 kinds of diversion?

23 **A.** Yes.

24 **Q.** And specifically with respect to the diversion of
25 opioids, what kind of diversion emerged?

1 **A.** After Congress passed *Ryan Haight*, we saw -- basically
2 shut down the brick and mortar pharmacies in the United
3 States who are facilitating internet sales. At that point
4 in time, we started seeing a massive increase in pain
5 clinics, rogue pain clinics.

6 **Q.** And what is a rogue pain clinic?

7 **A.** A rogue pain clinic is just that. It's a group of
8 doctors, of prescribers, that are operating in a clinic
9 setting, but they're really not providing medical care.
10 It's just a prescription mill.

11 You walk in. They might give you a cursory
12 examination. You pay cash and they -- they write the
13 prescriptions that you want, for the drugs you want.

14 **Q.** And where were these rogue pill mills?

15 **A.** They started in Florida and then they moved throughout
16 the United States.

17 **Q.** And did you deploy resources to address the internet
18 and then the pain mill pharmacies or the pill mill, sorry,
19 pharmacies?

20 MS. WICHT: Your Honor, I'll just object because I
21 don't believe the witness has used the term "pill mill".
22 So, I'm not sure where that's coming from. I could be wrong
23 about that.

24 MS. SINGER: I'm sorry. You're right.

25 I will rephrase the question, Your Honor.

1 THE COURT: He called it a prescription mill, I
2 believe. Prescription mill.

3 MS. SINGER: Or pain clinic.

4 THE COURT: I will sustain the objection to pill
5 mill.

6 BY MS. SINGER:

7 Q. All right. Mr. Rannazzisi, can you answer that
8 question modified, meaning did DEA modify resources to
9 address the internet pharmacies and then the pain clinics or
10 prescription mills that you were seeing?

11 A. Yeah. We -- yes, we did deploy resources. And we had
12 to because our resources had to be concentrated down in the
13 area of -- of the most activity, which would have been at
14 that point in time Florida. So, we deployed a significant
15 amount of manpower and deployed attorneys. We deployed
16 pretty much everything we needed to to run operations down
17 there, in addition to the manpower that we had in the Miami
18 Field Division.

19 Q. And so, how many officers are we talking about or how
20 many people?

21 A. Again, it was -- it was groups. Probably at any one
22 time 30 more personnel, maybe 40.

23 Q. And was that a big commitment for DEA at the time?

24 A. Yes.

25 Q. And have you heard the term "Oxy Express" during your

1 tenure at DEA?

2 **A.** Yes.

3 **Q.** And what do you understand that term to mean?

4 **A.** "Oxy Express" was a term given to people that go down
5 to Florida to visit pill mills. They might go three, four,
6 five at a time and then load up either by car, or by bus, or
7 even by plane and take the drugs back to where they came
8 from. But Oxy Express originally was the I-75 Corridor
9 going up into -- going up through Georgia, past Georgia, and
10 then spreading out into the Midwest.

11 **Q.** And have you also heard the term "Blue Highway"?

12 **A.** Yes.

13 **Q.** And what do you understand that term to mean?

14 **A.** Same concept, different -- different roads, but it's
15 the same concept. When -- the term "blue" is -- was taken
16 from a particular tablet that was blue that they were all
17 looking for, an Oxy 30 tablet, Oxy milligram -- 30-milligram
18 tablet. That's why they called it the Blue Highway.

19 **Q.** And in your experience were pills that were dispensed
20 either by internet pharmacies or prescription mills
21 transported to other states along, I think you said, the
22 I-75 Corridor?

23 **A.** Yes. That was the whole idea behind it. You go down,
24 you visit multiple pill mills, multiple prescription mills.
25 You get your drug from pharmacies in the area and you take

1 them back to wherever you came from. Some of these people
2 just got the prescriptions loaded up and then headed back
3 north to wherever they came from and had the prescriptions
4 actually filled at their local pharmacies.

5 **Q.** And what drugs were being distributed through these --
6 these prescription mills?

7 **A.** Well, we saw a massive shift in the types of drugs.
8 Everybody -- we were seeing large quantities of hydrocodone
9 during the internet phase of this problem. And then, we
10 started seeing oxycodone, specifically the high dose
11 oxycodone, 10-milligram, 15-milligram and 30-milligram
12 tablets coming out, the prescriptions coming out.

13 We did see a small -- you know, smaller amounts of the
14 other doses, but they were looking for 10-milligram, 15 and
15 30s when they were going down to Florida.

16 **Q.** And did DEA communicate to its registrants and to
17 distributors in particular that you were seeing this kind of
18 diversion of hydrocodone and oxycodone?

19 **A.** Yes. When we'd go out and do our presentations, that
20 was part of the presentations. If you look at the
21 presentations I've done throughout the country at different
22 -- different venues when I was with DEA, not after DEA, but
23 when I was with DEA, we always talked about oxy 15, oxy 30
24 and how the pill mills were operating. We were always
25 talking about looking at Alprazolam still because Alprazolam

1 was still being used in that trinity or that -- that trinity
2 of drugs with Carisoprodol and Oxycodone. We were talking
3 about all of that during that time period.

4 **Q.** And do you know --

5 THE COURT: Just a minute.

6 MS. WICHT: Your Honor, object to general
7 testimony about things that DEA purportedly was saying in
8 various places without any link to the defendants in this
9 courtroom, any link to Cabell-Huntington, any demonstrable
10 nexus to anything that happened here.

11 MS. SINGER: So, Your Honor --

12 MS. WICHT: And the objection is on the ground of
13 relevance.

14 THE COURT: Well, I will overrule the objection.
15 I think he's discussing the general situation here and
16 practices that embrace the entire operation of the
17 defendants, or at least McKesson, which would include the
18 geographical area at issue here. I will overrule the
19 objection.

20 Go ahead, Ms. Singer.

21 BY MS. SINGER:

22 **Q.** Do you know if these defendants were present at any of
23 these presentations that you provided?

24 **A.** I gave a lot of presentations to industry, to
25 pharmacists and industry. I can't tell you exactly if they

1 were present, but they had to know because I was not the
2 only one out there.

3 MS. WICHT: Objection, Your Honor, to what
4 defendants had to know. I'm sorry to interrupt the witness.

5 THE COURT: Sustained. If you can lay a basis of
6 what he really knew, you can ask him, but he's speculating
7 here as to what --

8 BY MS. SINGER:

9 Q. So, Mr. Rannazzisi, focusing on --

10 COURT REPORTER: I'm sorry. I didn't --

11 MS. SINGER: I'm sorry.

12 COURT REPORTER: -- get the end of that, Your
13 Honor. I'm sorry.

14 MS. SINGER: I'm sorry.

15 THE COURT: Go ahead, Ms. Singer.

16 MS. SINGER: I'm terribly sorry.

17 THE COUR: That's all right.

18 BY MS. SINGER:

19 Q. Mr. Rannazzisi, focusing on what DEA said, did DEA
20 provide through other staff, to your knowledge,
21 communications about the diversion of oxycodone and
22 hydrocodone that you just talked about?

23 MR. SCHMIDT: Objection, vague. I think they're
24 trying to cure a problem by suggesting we had this
25 information without laying that foundation. They're trying

1 to put in the testimony before they lay that foundation.

2 MS. SINGER: Your Honor, I think --

3 THE COURT: Well, overruled. You can ask him what
4 he -- what he knows and you said to your knowledge. If he
5 knows, he can answer.

6 THE WITNESS: The distributor meetings, the
7 distributor conferences that were done, this information was
8 presented.

9 BY MS. SINGER:

10 Q. Okay. Mr. Rannazzisi, shifting gear, what is -- do you
11 know the term "Immediate Suspension Order"?

12 A. Yes.

13 Q. What is an Immediate Suspension Order?

14 A. Immediate Suspension Order is -- generally, it is
15 always attached to an Order to Show Cause. So, I mean,
16 generally an Order to Show Cause, I -- I'm presented with a
17 number of violations and we decide that we're going to show
18 cause that the registrant, whoever it is, a doctor,
19 pharmacy, a distributor, and we give them the opportunity to
20 appear before an administrative law judge and show cause as
21 to why their registration should not be -- action should not
22 be taken against the registration.

23 Q. And were you responsible at DEA for initiating
24 immediate suspension orders during your tenure?

25 A. If I can continue, Order to Show Cause by itself is

1 just -- is just a notice and, when you come in, you can
2 still practice whatever you're doing, pharmacy, medicine,
3 whatever.

4 An Order to Show Cause with an Immediate Suspension
5 Order is different. At that point in time, I can stop you
6 from doing whatever you're doing with controlled substances.
7 So, if it's a distributor, I could stop them from
8 distributing controlled substances until they appear before
9 an administrative law judge and a final order is issued.
10 Same thing with a doctor. Same thing with a pharmacy.

11 So, now, what was the question, ma'am?

12 **Q.** Were you responsible for recommending or deciding on
13 Immediate Suspension Orders at DEA during your tenure?

14 **A.** What would happen at DEA is if an immediate suspension
15 -- if there was an Order to Show Cause, it would be my
16 responsibility to review the Order to Show Cause, determine
17 the violation, and sign off on the Order to Show Cause.

18 If it's an Immediate Suspension Order, I would review
19 the Immediate Order to Show Cause and the Immediate
20 Suspension Order and then it would be -- it would be sent to
21 the Deputy Administrator of DEA and they would make the
22 determination, but I would -- I would sign off on it before
23 it would go up to the Deputy Administrator.

24 **Q.** And what is the standard that DEA applied during your
25 tenure for initiating an Immediate Suspension Order?

1 **A.** An imminent threat to public health and safety.

2 **Q.** And can you explain what that means?

3 **A.** It means that while you're operating under our
4 registration, what you're doing and how you are doing your
5 position -- your job, be it being a pharmacy, or a doctor,
6 or a distributor, or a manufacturer, how you're doing your
7 job is an imminent threat because you're not maintaining
8 effective controls against diversion.

9 **Q.** And did you initiate Immediate Suspension Orders during
10 your tenure as Deputy Assistant Administrator?

11 **A.** I reviewed Orders to Show Cause and if I felt there was
12 an imminent threat, I would suggest that they go back and
13 look.

14 **Q.** And "they" in that answer is who?

15 **A.** Would be the investigators, but the vast majority of
16 the time they had already come to the conclusion it was an
17 imminent threat when it hit my desk.

18 **Q.** And did you make recommendations to the Deputy
19 Administrator during your tenure to issue Immediate
20 Suspension Orders against any of the defendant?

21 **A.** I made recommendations on the Order to Show Cause. I
22 didn't make recommendations. It was up to the
23 Administrator, the Deputy Administrator, to look at the four
24 corners of the document and make a determination there was
25 an imminent threat. That was solely in her purview.

1 Q. Okay. And I'm sorry because you had explained that.
2 Did you make recommendations with respect to Orders to Show
3 Cause related to these three defendants during your tenure?

4 A. Yes.

5 Q. And in recommending an Order to Show Cause what was
6 your goal as Deputy Assistant Administrator? What were you
7 trying to accomplish?

8 A. To stop the hemorrhaging. You know, when -- when we're
9 doing an Order to Show Cause, we don't take those lightly.
10 An Order to Show Cause is a significant step because there's
11 violations afoot that are causing large scale diversion and
12 it has to be addressed. So, an Order to Show Cause is that
13 step.

14 I talked to you. I briefed you. I told you what your
15 responsibilities are. And you continue to do it. So now,
16 you appear before an administrative law judge and the agency
17 and explain why you continue to do it.

18 Q. Did you reach a point during your tenure that you
19 recommended an Order to Show Cause against McKesson?

20 A. Yes. It was shortly after that meeting.

21 Q. And by "that meeting", what are you referring to?

22 A. January 3rd meeting.

23 Q. Of what year?

24 A. 2006.

25 MS. SINGER: Let's pull P-00016, please.

1 May I approach, Your Honor?

2 THE COURT: Yes.

3 BY MS. SINGER:

4 Q. Mr. Rannazzisi, do you recognize what has just been
5 shown to you as P-00016?

6 A. Yes.

7 Q. And what do you recognize it to be?

8 A. It looks like the administrative record for -- for the
9 initial McKesson Order to Show Cause.

10 Q. And did you recommend that Order to Show Cause to the
11 Deputy Administrator?

12 A. Yes. I -- yes.

13 Q. And can you turn to Page 6 of the document, please?

14 A. Yes.

15 Q. And is that your signature on Page 6 of the Order to
16 Show Cause?

17 A. Yes, it is.

18 Q. And do you know, referring just to the Order to Show
19 Cause, which I think is Pages 4 to 6, did DEA issue this
20 Order to Show Cause after a legally authorized
21 investigation?

22 A. Yes.

23 Q. And do you know whether this document sets forth the
24 findings of that investigation?

25 A. Yes, it does.

1 MS. SINGER: Your Honor, I would move to admit
2 just Pages 4 to 6, the Order to Show Cause that Mr.
3 Rannazzisi signed.

4 MR. SCHMIDT: Your Honor, we'll object to that
5 motion in terms of, number one, these are simply allegations
6 that were made in a court filing. Number two, the entire
7 court filing is McKesson's response to these allegations.
8 So, if it was going to come in, it would have to come in,
9 all of it, not just the cherry-picked allegations of the
10 government, but the governmental allegations themselves
11 should not come in.

12 THE COURT: So, you think I ought to admit the
13 whole file?

14 MR. SCHMIDT: I think none of it should come in,
15 but if anything comes in, it should all come in.

16 THE COURT: Ms. Wicht?

17 MS. WICHT: Your Honor, I'm rising only because I
18 saw Mr. Ackerman rise and I wanted to note that Ms. Singer
19 and Mr. Ackerman represent the same party in this case.
20 They work for the same law firm. And I believe that it
21 would be proper for there to be only one person objecting
22 and arguing objections during the examination. Thank you.

23 MR. ACKERMAN: Can I address that, Your Honor? I
24 will try to do it quickly.

25 THE COURT: Okay, go ahead.

1 MR. ACKERMAN: I don't think there's a rule that
2 they can cite that says one person can't argue objections.
3 We're trying to do this in order to keep -- in order to move
4 the trial along. We know we've got timing issues and this
5 is an efficiency issue.

6 THE COURT: Well, I took this up a long time ago
7 way back in the early history of this case and I think I
8 ruled that it was one lawyer per witness per party and I've
9 consistently violated that ruling, there being no objection
10 to it, but there's an objection now, so I'm going to sustain
11 Ms. Wicht's objection.

12 And it's up to you, Ms. Singer.

13 MS. SINGER: Oh, Your Honor, that breaks my heart.
14 All right. Maybe there could be an exception given that DOJ
15 is here so we've now got one more on that side, but I will
16 try to fill Mr. Ackerman's shoes.

17 THE COURT: Mr. Farrell?

18 MR. FARRELL: I'd be willing to lend my proxy to
19 Mr. Ackerman as counsel for Cabell County.

20 THE COURT: Well, I'm sure that's a generous
21 offer, but I don't think it falls within the purview of the
22 Court's ruling.

23 So, go ahead, Ms. Singer.

24 MS. SINGER: I will do my best, Your Honor.

25 MS. SINGER: Under FRE 8038(a)(1), this document

1 is a record of a public office that, quote, sets out the
2 office's activities.

3 THE COURT: Shouldn't the whole file come in
4 rather than just the part you've pulled out?

5 MS. SINGER: We -- we don't object to that, Your
6 Honor.

7 THE COURT: Is that what you want, Mr. Schmidt?

8 MR. SCHMIDT: If any of it comes in, that's what
9 we want. We maintain our objection to any of it coming in.

10 THE COURT: You object to all of this, but if I
11 let any of it in at all, you want it all in?

12 MR. SCHMIDT: Yes, Your Honor.

13 THE COURT: Okay. I'm going to admit P-00016.
14 It's admitted, the whole file.

15 BY MS. SINGER:

16 **Q.** When did DEA issue this Order to Show Cause against
17 McKesson?

18 **A.** The Order to Show Cause was issued August 4th.

19 **Q.** Of what year?

20 **A.** 2006.

21 **Q.** Take a drink, please.

22 **A.** May I have another bottle of water, please? Thank you.

23 THE COURT: Absolutely. Is there a bottle
24 anywhere?

25 THE WITNESS: Thank you.

1 THE COURT: Mr. Rannazzisi, do you need to take a
2 break?

3 THE WITNESS: Oh, no, I'm fine. As long as I have
4 water, I'm fine.

5 THE COURT: We usually go until 10:30. Is that
6 okay?

7 THE WITNESS: That's fine, Your Honor. That's
8 perfect, Your Honor.

9 THE COURT: All right. Go ahead, Ms. Singer.

10 BY MS. SINGER:

11 Q. Mr. Rannazzisi, can you say again what day, date and
12 year, was the Order to Show Cause issued?

13 A. August 4th, 2006.

14 Q. And that was, if I can do the math, eight months after
15 you met with McKesson on January 3rd, 2006?

16 A. Yes, ma'am.

17 Q. Okay. I'd like you to turn to Paragraph 5 on Page 2 of
18 the Order to Show Cause. And can you read that paragraph
19 out loud, please?

20 A. Subsequently, DEA officials reviewed ARCOS reports for
21 the period October 1st, 2005 to January 31st, 2006, and
22 found that seven Florida pharmacies were still acquiring
23 extraordinary quantities of hydrocodone. Despite its
24 knowledge of suspicious internet practices, McKesson
25 Lakeland was engaging -- or was engaged in a continuing

1 practice of supplying hydrocodone to these seven pharmacies.

2 **Q.** Now, did DEA seek -- so, I'm sorry. This Order to Show
3 Cause, did it also include a request for an immediate
4 suspension -- or Immediate Suspension Order?

5 **A.** I don't believe this one did, no.

6 **Q.** Okay. So, what were you seeking with this Order to
7 Show Cause?

8 **A.** I was seeking compliance, but I was also seeking an
9 explanation for why they weren't -- they weren't proceeding
10 in a manner that's compliant with the act and what -- the
11 direction we gave them.

12 **Q.** And the Order to Show Cause, I think, as you explained,
13 would seek the revocation of registration of the -- of the
14 revocation of the registration of McKesson's Lakeland
15 Distribution Center; is that right? Or explain what it
16 does.

17 **A.** Well, yeah. An Order to Show Cause is specific to a
18 DEA registration number, which is specific to a facility.
19 So, if the facility is the Lakeland Distribution Center,
20 that would be the only facility within the McKesson
21 Corporation that we were -- we were looking at. We were
22 seeking either a revocation or -- or some type of
23 modification to the registration.

24 **Q.** And was it -- was it your view at the time this Order
25 to Show Cause was filed that McKesson's noncompliance was

1 limited to the Lakeland Distribution Center?

2 **A.** Well, I only --

3 MR. SCHMIDT: Objection, foundation. We have here
4 a document where they proceeded against one distribution
5 center. It did not regularly supply Huntington-Cabell and
6 they're now trying to bootstrap that without a foundation
7 into a broader opinion from a fact witness.

8 THE COURT: Well, I --

9 MS. SINGER: Your Honor --

10 THE COURT: Go ahead.

11 MS. SINGER: I'm sorry.

12 THE COURT: Go ahead, please.

13 MS. SINGER: Two points, if I may. One, I would
14 ask that Mr. Schmidt not argue in terms of his objection
15 when there's been no testimony from this witness about where
16 it distributed.

17 But that said, Mr. Rannazzisi has testified that this
18 was a national system. I'm asking him to address his
19 knowledge of whether the problem was limited to Lakeland or
20 national.

21 MR. SCHMIDT: And I'm fine not having speaking
22 objections. There was just a speaking objection when the
23 witness was on the stand to hear the speaking objection.
24 So, I will object to foundation.

25 THE COURT: All right. I'll overrule the

1 objection. You can ask him.

2 BY MS. SINGER:

3 Q. Do you need me to re-state the question or do you have
4 it?

5 A. Yes. Please re-state the question.

6 Q. Did you believe that McKesson's noncompliance was
7 limited to the Lakeland Distribution Center?

8 A. The Lakeland Distribution Center was the target of this
9 Order to Show Cause, but as I testified previously, it was
10 my belief, based on what I knew, that it was a systemic
11 failure within their system.

12 Q. So, why then did DEA only seek an Order to Show Cause
13 against the Lakeland Distribution Center?

14 A. Because, at that point in time, that's where we found
15 the violations. That's where the violations -- we -- we --
16 when we went into those meetings, we set out a specific, a
17 very specific set of ARCOS data. We told them look at these
18 particular pharmacies from this particular center, okay, and
19 we expected them to comply with our guidance and, instead,
20 they continued to ship. So, that's why we took action
21 against that one specific distribution center.

22 THE COURT: Mr. Rannazzisi, why did you think it
23 was a systemic failure within McKesson's entire system?
24 What was the basis for that?

25 THE WITNESS: Because when I was briefed on the

1 systems before we went into the meeting, the second meeting,
2 I was told that the systems that they have are basically a
3 nationwide system. So, when I looked at the system and
4 looked at what they were doing, when they told us later on
5 it's not picking up generic products, it didn't make sense
6 that it was only at that facility because they were
7 operating a nationwide system.

8 MR. SCHMIDT: I will object to that portion of the
9 answer as hearsay.

10 THE COURT: Well, they -- if I understood his
11 testimony, the statements that he referred to were coming
12 from McKesson, so I will --

13 MR. SCHMIDT: No. I think what he referenced was
14 when I was briefed before that meeting was the language. I
15 don't have the live stream in front of me. That would not
16 have been from McKesson. That would have been from his
17 reports.

18 MS. SINGER: Your Honor, I think the testimony --

19 MR. SCHMIDT: And I think the witness is nodding
20 along.

21 COURT REPORTER: I'm sorry. I didn't hear that.

22 MR. SCHMIDT: I believe -- well, I shouldn't --
23 I'll just stand on what I said, Your Honor.

24 MS. SINGER: I think the witness is testifying as
25 to information that he had as a basis of an action he took

1 and the effect that that information had on his decision
2 making.

3 THE COURT: I'll overrule the objection. You can
4 proceed. I think he's already answered the question.

5 BY MS. SINGER:

6 **Q.** So, Mr. Rannazzisi, did DEA have resources -- or how --
7 how much -- how much time and resource does it take for DEA
8 to -- to initiate an Order to Show Cause?

9 **A.** It takes quite a bit of time because we have to -- we
10 kind of -- I've got to -- at this point in time, it's
11 difficult to talk about it because I'm prohibited from
12 talking about certain things. We create an administrative
13 record and --

14 MR. SCHMIDT: I'll object. If he's limiting his
15 answer, that means we can't cross examine him on this.

16 BY MS. SINGER:

17 **Q.** So, without -- if I may re --

18 THE COURT: Well, wait a minute. What about the
19 things that he is not permitted to answer, Ms. Singer?

20 MS. SINGER: So, Your Honor, I can make clear that
21 I'm not directing the question -- any law enforcement
22 sensitive information. I just want to know is it a major
23 commitment of resources.

24 THE COURT: Well, I think Mr. Rannazzisi
25 understands the limitations here.

1 Mr. Westfall?

2 MR. WESTFALL: I think he does understand, Your
3 Honor. He can't disclose the law enforcement sensitive
4 techniques that goes into the decision or deliberate
5 processes, so I think he understands that.

6 THE COURT: Well, I don't think he's there yet,
7 Mr. Schmidt.

8 MR. SCHMIDT: We do object to the continuing
9 testimony on behalf of the DEA. He's not here on behalf of
10 the DEA and he continues to state what sounds like opinions
11 on behalf of the DEA.

12 THE COURT: All right. Overruled.

13 Ms. Wicht?

14 MS. WICHT: Your Honor, I would add that I --
15 looking at the Touhy authorization that we have for Mr.
16 Rannazzisi to be here today, it's not clear to me how this
17 topic fits within the scope of what's been authorized.

18 MS. SINGER: Your Honor, I don't know that a party
19 other than the Department of Justice has standing to object
20 on the scope of a Touhy authorization.

21 THE COURT: Well, that's right. I'm going to rely
22 on Mr. Westfall here and I will overrule your objection, Ms.
23 Wicht. And Fred's on his feet back there.

24 MR. WESTFALL: Your Honor, under the authorization
25 he's allowed to testify about his personal recollection

1 related to the enforcement with regard to the defendants and
2 his interactions with them but, again, with the caveat that
3 we explained that we can't release law enforcement sensitive
4 techniques and privileged information.

5 THE COURT: Okay.

6 MR. WESTFALL: So, he's limited in that regard.
7 And I don't know if, Your Honor, if it would help the Court.
8 I have an extra copy of the Touhy letter that was sent to
9 him if that would help the Court in considering any of the
10 objections of the parties.

11 THE COURT: Well, I think I have a copy of that
12 letter here somewhere.

13 I think we all understand the limitations here. So,
14 you go ahead, Ms. Singer.

15 BY MS. SINGER:

16 **Q.** Okay. Mr. Rannazzisi, I think the question before you
17 is, is it a big commitment of resources for DEA to -- to
18 move forward with an Order to Show Cause?

19 **A.** Yes, it is a very large commitment of resources.

20 **Q.** And speaking to your knowledge, is the fact that DEA
21 took action against only one distribution center or a few
22 distribution centers an indication that there weren't
23 problems in other distribution centers?

24 **A.** No. As I had testified before, the focus of this Order
25 to Show Cause was based on what we saw in this distribution

1 center. That doesn't mean that other distribution centers
2 weren't involved. It doesn't mean they were involved. Just
3 that this distribution center was where the violations were
4 at the time.

5 MS. SINGER: Okay. Let's turn to P-23733.

6 Sorry. May I approach, Your Honor?

7 BY MS. SINGER:

8 Q. All right. Mr. Rannazzisi, do you recognize P-23733?

9 A. Yes, I do.

10 Q. And what do you recognize that document to be?

11 A. This is a Settlement and Release Agreement.

12 Q. And with -- among whom?

13 A. With McKesson. Between McKesson and DEA.

14 Q. Okay. And are you familiar with this Settlement
15 Agreement from your time at DEA?

16 A. Yes, sir. [Sic] Yes, ma'am. Yes, ma'am.

17 Q. Oh, you've done that twice now. I'm going to keep
18 track.

19 A. I know. I'm sorry.

20 Q. I wish I'd say it was the worst thing somebody had
21 called me.

22 A. No, no, no. I'm sorry. I apologize.

23 Q. Before we go into this Settlement Agreement, this has
24 already been admitted into evidence. I wanted to just go
25 back for a second. How many distribution centers do

1 defendants operate?

2 **A.** It depends on the defendant. I guess -- I guess, you
3 know, more than 20. You know, the number 26 or 27 comes up,
4 comes to mind. But, you know, I just can't tell you for
5 sure, but a lot, because they're operating nationwide.
6 They're out there distributing all across the country. So,
7 you know, more than 20, less than 50. How about that?

8 **Q.** And do you have facts within your personal knowledge to
9 indicate whether these -- these compliance systems you've
10 been talking about were centrally located?

11 **A.** Well, it depends on the -- on the distributor.

12 **Q.** And how about for these defendants?

13 **A.** I believe -- yes. I think all three defendants have a
14 centrally located system. They operated the systems out of
15 their distribution centers, but they were centrally located.

16 **Q.** And the system design and management happened
17 centrally, to your knowledge, or was that distributed?

18 **A.** I'm sorry. Could you repeat that?

19 **Q.** Was the design and implementation of each of
20 defendants' compliance systems managed out of the central
21 headquarters, if you know?

22 **A.** I -- I couldn't tell you if it was centrally managed
23 out of headquarters or not.

24 **Q.** All right. Let's turn back to the Settlement
25 Agreement, P-23733. After the McKesson Lakeland Order to

1 Show Cause, did you subsequently issue Orders to Show Cause
2 for McKesson's Distribution Center elsewhere?

3 **A.** Yes.

4 **Q.** And which distribution center was that?

5 **A.** Landover, Maryland.

6 **Q.** And where's -- okay. And did you sign that Order to
7 Show Cause?

8 **A.** Yes, I did.

9 **Q.** And did you also find a failure to maintain effective
10 controls in McKesson's Conroe, Texas Distribution Center?

11 **A.** Yes.

12 MR. SCHMIDT: Objection. There's a difference
13 between issuing an Order to Show Cause and some suggestion
14 that the DEA has made a finding.

15 BY MS. SINGER:

16 **Q.** MR. Rannazzisi --

17 THE WITNESS: There's no -- there was no Order to
18 Show Cause issued in Conroe. Conroe was an add-on to this
19 memorandum.

20 **Q.** Okay. But --

21 MR. SCHMIDT: Even more so then, I object, Your
22 Honor. There was no finding.

23 BY MS. SINGER:

24 **Q.** Mr. Rannazzisi, what is the document --

25 THE COURT: Overruled. Go ahead, Ms. Singer.

1 MS. SINGER: Okay. I'm sorry.

2 BY MS. SINGER:

3 Q. What does the document say with respect to the Conroe,
4 Texas Distribution Center at Page 1?

5 A. DEA alleges that McKesson failed to maintain effective
6 controls against -- at its Conroe, Texas Distribution
7 Center, the Conroe facility, against diversion of a
8 particular controlled substance into other legitimate
9 medical, scientific and industrial channels by sales to
10 certain customers of McKesson.

11 Q. Okay. So, you see on the screen Landover and the
12 paragraph below that is Conroe, correct?

13 A. Yes.

14 Q. And then let's turn to Page 2. Can you read the top of
15 at that paragraph, please?

16 A. Whereas DEA alleges that McKesson failed to maintain
17 effective controls at its Denver, Colorado Distribution
18 Center, the Denver facility, against diversion of particular
19 controlled substances into other than legitimate medical,
20 scientific and industrial channels by sales to certain
21 customers of McKesson.

22 Q. Okay. So, we've now talked about several McKesson
23 Distribution Centers; is that correct?

24 A. Four, yes.

25 Q. Okay. So, let's turn to the bottom of Page 1, please,

1 Paragraph 2, where it says covered conduct.

2 **A.** Okay.

3 **Q.** Are you with me?

4 **A.** Yes.

5 **Q.** Okay. And can you -- can you read the definition of
6 covered conduct starting at (1)?

7 **A.** Covered conduct. For purposes of this agreement,
8 covered conduct shall mean the following: The conduct
9 alleged in the orders.

10 **Q.** Okay. And then moving to the next page, please?

11 **A.** The alleged failure of McKesson to maintain adequate
12 controls against the diversion of controlled substances on
13 or prior to December 31st, 2007 at all distribution
14 facilities operated, owned, or controlled by it.

15 **Q.** And then why don't you skip, please, to Paragraph 4?

16 **A.** The alleged failure of McKesson to detect and report
17 suspicious orders of the controlled substances as required
18 by 21 C. F. R. 1301.7(4)(b) on or before December 31st,
19 2007.

20 **Q.** And I'd like you to turn to Paragraph 6, please, on the
21 following -- on the following page, I believe. Yes. So,
22 Page 4, if you look at (e), can you read that paragraph, as
23 well?

24 **A.** McKesson agrees that any express or implied approval by
25 DEA of any previously implemented system to detect and

1 report suspicious orders is hereby rescinded and is of no
2 legal effect with respect to McKesson's obligations to
3 detect and report suspicious orders in accordance with 21 C.
4 F. R. 1301.74(b).

5 **Q.** And do you know why DEA included this provision in the
6 agreement?

7 **A.** Yes, I do.

8 **Q.** And --

9 **A.** There was -- there was --

10 MR. WESTFALL: Your Honor, again, I would object
11 to the extent that they're (unintelligible).

12 COURT REPORTER: I can't hear. I'm sorry.

13 MR. WESTFALL: I'm sorry.

14 I object to the extent we're getting into
15 attorney-client privilege information as to why this was
16 included and also a deliberate process in law enforcement
17 sensitive information. He can talk about what's publicly
18 known and certainly why, but as far as any of these other
19 areas that are privileged, he can't disclose those.

20 MR. SCHMIDT: I would note, Your Honor, not to
21 argue with the privilege claim, Mr. Rannazzisi has given
22 testimony under oath in answer to this question.

23 MR. WESTFALL: And I don't have a problem, Your
24 Honor, with him disclosing what he's testified under oath.
25 That's not -- that's not an issue.

1 THE COURT: Well, I don't think he's reached the
2 forbidden area here, so let's go on from here and see where
3 we go.

4 MR. WESTFALL: Thank you, Your Honor.

5 MS. SINGER: Mr. Schmidt agrees. Now I'm nervous
6 about the question, Your Honor, but I'll go ahead.

7 BY MS. SINGER:

8 Q. Mr. Rannazzisi, can you answer consistent with --

9 A. Can you repeat the question, please.

10 Q. Do you know why this provision was included in this
11 agreement?

12 A. Because there was information out there that DEA was
13 approving Suspicious Order Monitoring Programs and that was
14 not correct and not true.

15 MR. SCHMIDT: And I'll object to the second half
16 of the question on foundation. Second half of the answer.
17 I apologize.

18 MS. SINGER: "And that was not true"?

19 MR. SCHMIDT: Yes, because it pre-dates his role.

20 THE COURT: Wait just a minute.

21 MR. SCHMIDT: And because he's acknowledged he
22 doesn't know what happened prior to him taking --

23 THE COURT: Well, I will sustain the objection to
24 the foundation. Maybe you can clear it up.

25 MS. SINGER: All right.

1 BY MS. SINGER:

2 Q. Mr. Rannazzisi, during your tenure at DEA and around
3 the time of this Settlement Agreement, did you have
4 information that caused you to believe that there was a
5 belief that DEA was approving suspicious order monitoring
6 systems?

7 A. Yes. That was the information that was not correct.

8 Q. And so, what --

9 MR. SCHMIDT: And, again, Your Honor, after Your
10 Honor just sustained a statement from him, he just made the
11 same statement that that's correct. That does not have a
12 foundation.

13 MR. NICHOLAS: I'll join in this objection, Your
14 Honor, on the basis of foundation for ABDC.

15 MR. SCHMIDT: And, Your Honor, may -- sorry.

16 THE COURT: I'll sustain the objection.

17 BY MS. SINGER:

18 Q. So, Mr. Rannazzisi --

19 THE COURT: You've got to show how he knew, if you
20 can.

21 MS. SINGER: Okay.

22 THE COURT: And what the basis was.

23 BY MS. SINGER:

24 Q. So, how did you know that that -- I'm sorry. Did you
25 have -- did you have reason to believe that -- I'm sorry.

1 How do you know, Mr. Rannazzisi?

2 MR. SCHMIDT: And objection, Your Honor. She's
3 asking him to explain an answer that's been struck. The
4 answer is struck, so he can't explain how he knew something
5 that -- they've got to lay the foundation first, not accept
6 the answer as true and then ask him to explain how it's
7 true.

8 THE COURT: Well, if she can do it, I'll give her
9 the chance do it. Go ahead.

10 MS. SINGER: All right.

11 BY MS. SINGER:

12 Q. I think third try, hopefully, Mr. Rannazzisi.

13 Mr. Rannazzisi, how -- how did you know that -- that --
14 did you know that these defendants, let's focus on these
15 defendants, had a belief -- I'm going to try again.

16 Striking that, did defendants, to your knowledge,
17 suggest that DEA had approved prior suspicious order
18 monitoring systems?

19 A. Yes. There were some -- yes.

20 Q. And how did you know that?

21 A. Because my staff advised me that we need to make it
22 clear that we're not approving those systems.

23 Q. And to your knowledge -- sorry. Strike the to your
24 knowledge. Did DEA approve suspicious order monitoring
25 systems?

1 MR. SCHMIDT: And this is where this is pure
2 hearsay. As an expert witness, Your Honor -- may I explain
3 my objection?

4 THE COURT: Yes. Please go ahead.

5 MR. SCHMIDT: As an expert witness he purported to
6 go back and review materials before his time. We believe
7 those materials actually support him -- support us, I'm
8 sorry, but the key, whatever the debate is over those
9 materials, is that he did not review them in the course of
10 his work. He acknowledged that he reviewed them to serve as
11 an expert witness.

12 He came into his role in '05 and '06. If he wants to
13 -- he should be able to testify about his knowledge from
14 that time period, including being told in that time period
15 that people understood they had approval from the DEA, but
16 to go back and try to say that that was incorrect when he
17 was not involved in that time period and has acknowledged
18 that he only learned about that time period to serve as an
19 expert is improper.

20 THE COURT: Mr. Nicholas?

21 MR. NICHOLAS: I think we may, in part, be talking
22 about the approval of AmerisourceBergen's Suspicious Order
23 Monitoring System from 1998.

24 And just to buttress what Mr. Schmidt has said, this
25 witness has already testified with regard to that approval

1 that he did not -- he had not spoken to any of the people
2 that were involved in the putting together of that program
3 or the approval of that program. He's testified about that
4 in a different matter.

5 So, I -- I agree and second Mr. Schmidt's objection on
6 this basis.

7 MS. SINGER: So, Your Honor -- and now that we
8 don't have Mr. Ackerman, I fear we have Mr. Farrell. But in
9 any event, I have asked the witness about his knowledge
10 during his time period. I don't know that we want to spend,
11 I certainly don't, much more time on this issue. I'm simply
12 seeking to ask the witness his understanding. He's
13 testified to that and the basis for his understanding to his
14 knowledge.

15 BY MS. SINGER:

16 Q. And, Mr. Rannazzisi, I'm happy to make clear I'm based
17 -- I'm asking my question about what you knew during your
18 tenure at DEA and not anything you've learned since you
19 left.

20 MR. SCHMIDT: Your Honor, the objection is that
21 would be pure hearsay. We know from testimony from I think
22 witnesses from every company that they believed their
23 systems were approved by the DEA. We know that Mr.
24 Rannazzisi felt a need to rescind that in this letter and in
25 other sources because it was true.

1 For him to say I was told they didn't really get
2 approval, that's pure hearsay. There's no foundation that
3 can be laid for that and it's something he's tried to do as
4 an expert and it's bringing in expert testimony.

5 MR. NICHOLAS: The witness was asked -- what the
6 witness said was in response to a question that the DEA did
7 not approve suspicious order monitoring systems. That, I
8 don't believe he can say based on -- based on the
9 limitations of his testimony -- to his testimony as a fact
10 witness in a -- in a defined period of time.

11 THE COURT: Ms. Wicht, do you want to make it
12 unanimous here?

13 MS. WICHT: That's all I was looking to do, Your
14 Honor. I don't believe I need to do this under the
15 protocols if we have in place but I just on this particular
16 issue wanted to make sure I stood up and said that we join
17 in the objections.

18 THE COURT: And, Mr. Farrell, I don't have my
19 score card. You represent a different party from Ms.
20 Singer?

21 MR. FARRELL: Yes, Your Honor.

22 THE COURT: Okay. I'll hear from you.

23 MR. FARRELL: This is also a subject that is
24 discussed at length in the DEA 30(b)(6) deposition of Thomas
25 Prevosnik which includes the manuals from '96 moving

1 forward. And so, this is within the purview of the role of
2 Mr. Rannazzisi and consistent with facts that are already in
3 the record. This is not an expert opinion, Judge. We would
4 submit that in the Prevosnick deposition this would be a
5 fact.

6 MR. SCHMIDT: The fact that a witness who had
7 factual knowledge testified about that doesn't give Mr.
8 Rannazzisi that knowledge.

9 MS. SINGER: Well, Mr. Rannazzisi has testified,
10 Your Honor, that he has that knowledge and I would suggest
11 that if defendants wish to cross examine, they will no doubt
12 have ample time to do that, but I think this has turned into
13 legal argument when Mr. Rannazzisi has testified as to what
14 he knew and did at DEA.

15 THE COURT: Let's start here and go around this
16 way.

17 MS. WICHT: I'll just add with respect to Mr.
18 Prevosnik, Your Honor, that that is, in fact, some of the
19 testimony from Mr. Prevosnik that there is a pending motion
20 to strike on the basis of lack of personal knowledge.

21 THE COURT: Mr. Schmidt?

22 MR. SCHMIDT: I think he's testified if he had
23 that knowledge at all it was told to him. It was hearsay.

24 MR. NICHOLAS: Nothing to add.

25 THE COURT: Well, if I understood him correctly,

1 he said that the basis for the opinion on the approval of
2 the suspicious ordering systems was what he had been told by
3 others and that's hearsay and I'm going to sustain the --
4 use Occam's razor here and go straight to that one ground
5 and sustain the objection.

6 You can move on, Ms. Singer.

7 MS. SINGER: All right. Understood.

8 BY MS. SINGER:

9 Q. Mr. Rannazzisi, just to go back for one second, prior
10 to beginning or at any point during your tenure at DEA did
11 you go back and look at DEA's prior guidance to
12 distributors?

13 A. I was briefed on prior guidance at one point in time.

14 Q. And during your tenure as Deputy Assistant
15 Administrator, do you believe that the guidance you provided
16 and DEA provided under your direction was consistent with
17 DEA's past guidance to distributors?

18 MR. SCHMIDT: Objection, hearsay. He was asked
19 very specifically did you review it. Instead of saying he
20 reviewed, it he said, "I was briefed on it."

21 THE COURT: Sustained.

22 MS. SINGER:

23 Q. All right. Let's turn to the substance of the -- let's
24 turn to one other provision in the Memorandum of Agreement,
25 Page 6, Paragraph F, please. Are you there, Mr. Rannazzisi?

1 **A.** Yes.

2 **Q.** Okay. And what does this Paragraph F discuss?

3 **A.** Discusses the compliance reviews that are being done by
4 DEA to ensure that they're operating within the guidance of
5 the memo.

6 **Q.** And by memo, you mean the Settlement Agreement?

7 **A.** The Settlement Agreement, yeah.

8 **Q.** Okay. And can you read the last sentence of Paragraph
9 F, please?

10 **A.** In the event that DEA provides such written notice of a
11 compliance review failure, DEA shall meet and confer with
12 McKesson --

13 **Q.** Mr. Rannazzisi --

14 **A.** Oh, I'm sorry. That's the wrong one.

15 A finding of satisfactory does not otherwise express
16 DEA's approval of the compliance program implemented at any
17 particular distribution center.

18 **Q.** Okay. We'll come back to that point later. All right.
19 We can put aside this Settlement Agreement.

20 After the distributor initiative and the McKesson Order
21 to Show Cause did DEA file another Order to Show Cause
22 against one of the defendants here?

23 **A.** Yes.

24 **Q.** And did DEA file an Order to Show Cause against
25 AmerisourceBergen after the McKesson Order to Show Cause?

1 **A.** Yes. There was -- I don't recall the exact date, but
2 there was an Order to Show Cause filed against
3 AmerisourceBergen.

4 **Q.** And are you familiar with the Order to Show Cause that
5 DEA filed against AmerisourceBergen?

6 **A.** Yes.

7 MS. SINGER: Okay. Let's pull P-00049, please.
8 Your Honor, may I approach?

9 THE COURT: Yes.

10 BY MS. SINGER:

11 **Q.** All right. Mr. Rannazzisi, what is P-00049?

12 **A.** This is an Order to Show Cause and Immediate Suspension
13 of Registration, an Immediate Suspension Order.

14 **Q.** Against which defendant?

15 **A.** Against AmerisourceBergen.

16 **Q.** And what is the date of this Order to Show Cause?

17 **A.** April 19th, 2007.

18 **Q.** Okay. And this one, I think, as you indicated, also
19 included an Immediate Suspension Order; is that correct?

20 **A.** Yes.

21 **Q.** And did you recommend to the Deputy Administrator that
22 DEA initiate this Order to Show Cause, an Immediate
23 Suspension Order?

24 **A.** Again, I reviewed the Order to Show Cause and initialed
25 off on it and sent it up for review.

1 Q. Okay.

2 A. Put my initials on it.

3 Q. Excuse me?

4 A. My initials on it meant that it was -- that I had
5 reviewed it and I didn't find problems with it.

6 Q. Okay. And in this Order to Show Cause and Immediate
7 Suspension Order, did it lay out the specific conduct that
8 DEA believed violated the Controlled Substances Act?

9 A. Yes.

10 Q. And can you turn to Paragraph 5 at the top of Page 3?
11 And I direct you to notwithstanding. Do you see that at the
12 top of Page 3?

13 A. Yes.

14 Q. And can you read that sentence out loud, please?

15 A. Notwithstanding the information provided to respondent,
16 after the August 10th, 2005, meeting.

17 Q. And let me interject for just one second. Was the --
18 what was the August 10th, 2005 meeting?

19 A. It was a distributor initiative meeting.

20 Q. Okay. Keep going. I'm sorry.

21 A. Respondent sold over 5.2 million dosage units of
22 hydrocodone to pharmacies that bore the characteristics that
23 DEA described in the August 10th meeting.

24 Q. And so, to your knowledge, did AmerisourceBergen
25 continue to sell hydrocodone to -- to pharmacies even after

1 the date of the Immediate Suspension Order?

2 **A.** Yes, ma'am.

3 **Q.** I'm sorry. Even as to the date --

4 **A.** As to the date, yes.

5 **Q.** -- of the Immediate Suspension Order? And is that the
6 same conduct you had seen with McKesson prior to its Order
7 to Show Cause meeting a continuation of selling to
8 problematic pharmacies even after warned?

9 **A.** Yes.

10 **Q.** And had you concluded in initialing the Order to Show
11 Cause an Immediate Suspension Order against
12 AmerisourceBergen that the distribution of controlled
13 substances by AmerisourceBergen's Distribution Center
14 represented an imminent threat to public safety?

15 **A.** Well, again, that's up to the administrator to
16 determine whether there's an imminent threat to public
17 health, the Deputy Administrator. However, I did initial it
18 when I was -- I chopped off, or initialed, whatever you want
19 to say, on the total package, yes.

20 **Q.** And did that express your agreement that this conduct
21 was -- represented an imminent threat to public safety?

22 **A.** Well, I wouldn't have signed it if I didn't believe it
23 to be accurate, or initialed it.

24 **Q.** And -- and did you -- had you found that -- had DEA
25 found that these violations by AmerisourceBergen were

1 systemic, as well?

2 MR. NICHOLAS: Your Honor, I will object to this
3 question on the basis of lack of foundation. I guess the
4 other ground I will object to is that the witness has
5 already testified that this ISO is limited to this
6 distribution center and without more.

7 MS. SINGER: So, I don't think he has testified
8 yet, but --

9 THE COURT: Well, you need to lay a foundation for
10 it, but if you can, I'll allow him to answer.

11 BY MS. SINGER:

12 Q. And had -- had DEA, to your knowledge, had a chance to
13 observe AmerisourceBergen's compliance with the Controlled
14 Substances Act, its anti-diversion program?

15 MR. NICHOLAS: I will object, Your Honor. That's
16 too vague.

17 THE COURT: Overruled.

18 THE WITNESS: Could you repeat the question one
19 more time?

20 MS. SINGER: Yes.

21 BY MS. SINGER:

22 Q. Did DEA have a chance to observe AmerisourceBergen's
23 compliance with the Controlled Substances Act and its
24 anti-diversion program?

25 THE COURT: What period of time are we talking

1 about here?

2 MS. SINGER: Prior. I'm sorry, Your Honor. Prior
3 to the 2007 Order to Show Cause and Immediate Suspension
4 Order.

5 MR. NICHOLAS: I will renew my objection based on
6 vagueness and time period.

7 THE COURT: All right. Overruled. He can answer
8 if he can.

9 THE WITNESS: The distributor initiative was based
10 on the systems that they were operating. That's why they
11 were called in, because we wanted to make sure that they
12 understood what their obligations were, and to make the
13 appropriate corrections to their -- their systems. So --
14 so, yes, I was aware of this system at that point in time.
15 I was aware of all three, you know, the systems that they
16 had.

17 BY MS. SINGER:

18 **Q.** And by all three, what do you mean, Mr. Rannazzisi?

19 **A.** The three defendants.

20 **Q.** And did you have reason to believe -- did you believe
21 at the time that this Order to Show Cause and Immediate
22 Suspension Order was issued that AmerisourceBergen's conduct
23 was -- that its compliance deficiencies were national and
24 systemic?

25 MR. NICHOLAS: Your Honor, I will object. I've

1 listened carefully to the question and the answer. There is
2 no basis -- there is no foundation laid here for this
3 witness to answer that question.

4 MS. SINGER: I think, Your Honor, he has just
5 testified that he was familiar with all of their systems.

6 MR. NICHOLAS: That is all he has said about
7 AmerisourceBergen's program, is that he was familiar with
8 the system and the fact that they had a system, period.
9 Full stop.

10 THE COURT: Well, I'm going to overrule the
11 objection and let him answer.

12 THE WITNESS: When the system did not identify
13 these -- these orders as suspicious, I took that to be,
14 again, a systemic failure in their system and, therefore,
15 their system was not operating within the confines of
16 1301.74(b) to identify and report suspicious orders.

17 Q. So, let's turn --

18 MS. WICHT: Your Honor, I object to the legal
19 conclusion stated by the witness.

20 MR. NICHOLAS: Yes. I was --

21 MS. WICHT: Sorry, Mr. Nicholas.

22 MR. NICHOLAS: Forgive me. I should have been the
23 first one to make that objection, but that is the objection
24 I would make, as well.

25 THE COURT: And I will sustain that objection.

1 MS. SINGER: So, Your Honor, I would ask that --
2 that the witness's testimony up until the legal conclusion
3 be committed -- be permitted, meaning -- and I'm happy to
4 ask him again and with Your Honor's instruction that he not
5 offer a legal conclusion.

6 THE COURT: Well, ask him again and --

7 MR. NICHOLAS: Well, I'm standing up just in case.
8 I don't know what -- I don't know what she's going to ask.

9 THE COURT: Well --

10 MS. SINGER: But you assume you're not going to
11 like it, so fair enough.

12 THE COURT: Ask him the question and see if you
13 can get around the legal conclusion.

14 MS. SINGER: All right.

15 BY MS. SINGER:

16 Q. All right. Mr. Rannazzisi, prior to the time that this
17 Order to Show Cause and Immediate Suspension Order was
18 issued -- now I have to remember the question -- had you
19 reached a conclusion --

20 MS. SINGER: I'm sorry. Can I ask the court
21 reporter to read back the question that I originally asked?
22 Mr. Rannazzisi may be doing fine, but I may need a break,
23 Your Honor.

24 (Court reporter read back requested portion)

25 BY MS. SINGER:

1 **Q.** So, let me ask that question again. Did you have
2 reason to -- did you believe prior to the Order to Show
3 Cause and Immediate Suspension Order that
4 AmerisourceBergen's compliance deficiencies were national
5 and systemic?

6 **A.** Based upon --

7 MR. NICHOLAS: I object. I'm sorry, Mr.
8 Rannazzisi. Forgive me.

9 THE WITNESS: That's all right.

10 MR. NICHOLAS: I object both on the basis of lack
11 of foundation and specifically because there's no time
12 limitation being placed on this question. I don't think
13 this witness is in a position to provide any personal
14 information that pre-dates 2005 when he -- when he took over
15 his -- in his role here. So, I object on that basis.

16 The question did not limit -- had no time limitation
17 and, in addition, I do believe that there's no foundation
18 that's been laid here.

19 THE COURT: I'm going to overrule the objection
20 and let him answer, Ms. Singer, and get you off the hook
21 here.

22 MS. SINGER: Thank you.

23 THE WITNESS: Could you repeat the question one
24 more time?

25 MS. SING: Oh, that's sad.

1 MR. NICHOLAS: No, I will not -- I'm going to just
2 -- I'm going to -- I'm going to ask that my -- I'm not going
3 to object this time around. I just want to -- provided that
4 my objection is sort of preserved for the record.

5 THE COURT: Well, your objection is loud and clear
6 on the record, Mr. Nicholas, and it will be shown.

7 BY MS. SINGER:

8 **Q.** Did you believe, Mr. Rannazzisi, that prior to the
9 Order to Show Cause and Immediate Suspension Order against
10 AmerisourceBergen that the conduct that was described in
11 that order was nationwide and systemic?

12 **A.** As previously testified, the amounts of drugs that were
13 not identified during -- by their systems at the Orlando
14 facility or wherever they were operating was -- it was a
15 total breakdown of system and, therefore, systemic
16 throughout their -- their systems in general throughout the
17 country.

18 THE COURT: Is this a good place for a time-out?

19 MS. SINGER: Yes, Your Honor.

20 THE COURT: Okay. We will be in recess for ten
21 minutes.

22 You can step down, Mr. Rannazzisi.

23 THE WITNESS: Thank you very much, Judge.

24 (Recess taken)

25 (Proceedings resumed at 10:34 a.m. as follows:)

1 MS. SINGER: May I proceed, Your Honor?

2 THE COURT: Yes.

3 BY MS. SINGER:

4 Q. Mr. Rannazzisi, I want to show you P-00009.

5 MS. SINGER: May I approach, Your Honor?

6 THE COURT: Yes.

7 BY MS. SINGER:

8 Q. Mr. Rannazzisi, do you recognize this document?

9 A. Yes, I do.

10 Q. And what do you recognize this document to be?

11 A. A Settlement and Release Agreement.

12 Q. Between who?

13 A. AmerisourceBergen and the Drug Enforcement
14 Administration.

15 Q. And did you review this agreement while you were at
16 DEA?

17 A. Yes.

18 Q. All right. Let's turn -- I'm sorry. Do you know the
19 date of this agreement?

20 A. June 22nd of 2007.

21 Q. Let's turn to Page 2 of the agreement, if you could
22 look at Paragraph 3, "Covered Conduct." Can you read that
23 paragraph out loud, please?

24 A. "Covered conduct shall mean the conduct alleged in the
25 order and/or the modified order --"

1 Q. Let me interject for a second. What does that order or
2 modified order refer to?

3 A. The Order to Show Cause.

4 Q. The one you were just talking about?

5 A. Yes.

6 Q. Okay, all right. Keep going, please.

7 A. "-- the alleged failure of AmerisourceBergen to
8 maintain adequate controls against diversion of controlled
9 substances, on or prior to May 22nd 2007, at the Orlando
10 facility and all other distribution facilities controlled by
11 AmerisourceBergen, with respect to all sales of Automation
12 of Reports and Consolidated Orders System reportable
13 controlled substances, benzodiazepines and phentermine; and,
14 three, the alleged failure to detect and report suspicious
15 orders of sales of the controlled substances set forth in
16 Subsection I(3)(ii) of this agreement as required by 21,
17 C.F.R., 1301.74(b)."

18 Q. Were these -- did these controlled substances described
19 in this agreement include opioids?

20 A. Yes.

21 Q. And were these serious -- was this serious conduct that
22 this Settlement Agreement was resolving?

23 MR. NICHOLAS: Objection, no foundation and vague.

24 THE COURT: Sustained.

25 BY MS. SINGER:

1 **Q.** Mr. Rannazzisi, were you familiar with the nature
2 of the conduct that this Settlement Agreement was
3 resolving?

4 **A.** Yes.

5 **Q.** And was it serious misconduct in your eyes?

6 MR. NICHOLAS: Same objection.

7 THE COURT: Sustained.

8 BY MS. SINGER:

9 **Q.** Does this agreement reflect the conduct that DEA
10 had observed with respect to AmerisourceBergen?

11 MR. NICHOLAS: Objection, unclear, lack of
12 foundation.

13 THE COURT: Well, I think he's got to define his
14 understanding of serious misconduct, Ms. Singer.

15 MS. SINGER: I'm sorry, Your Honor. Can you
16 repeat that?

17 THE COURT: I think he needs to define, if he can,
18 what his understanding of serious misconduct is.

19 MS. SINGER: Okay.

20 BY MS. SINGER:

21 **Q.** And, Mr. Rannazzisi, you started to testify about
22 the nature of the conduct. What do you mean by serious
23 misconduct? What is that to you?

24 **A.** Allowing the diversion of hundreds of thousands of
25 dosage units into the illicit market. That's serious

1 misconduct, allowing diversion to occur.

2 Q. And --

3 MR. NICHOLAS: Your Honor, I'll object to, to --
4 and ask that the answer be struck. There's no foundation
5 for it.

6 THE COURT: Well, overruled.

7 Go ahead, Ms. Singer.

8 BY MS. SINGER:

9 Q. And was the conduct that this Settlement Agreement
10 with AmerisourceBergen resolved serious as you've
11 defined it?

12 MR. NICHOLAS: I'm sorry to continue to object.
13 These are allegations. They're not proven out. There's no
14 evidence of diversion that's been established here and I
15 will object.

16 THE COURT: I'll overrule the objection and you
17 can go ahead, Ms. Singer.

18 THE WITNESS: This was based on the Order to Show
19 Cause. The Order to Show Cause had hundreds of thousands --

20 COURT REPORTER: I'm sorry. Can you speak up just
21 a little?

22 THE WITNESS: I'm sorry.

23 It's based on the Order to Show Cause. The Order to
24 Show Cause detailed hundreds of thousands of tablets going
25 downstream. So, yeah, that's -- it's an Order to Show Cause

1 and those are very serious violations.

2 MR. NICHOLAS: Same objection for the same
3 reasons, Your Honor.

4 THE COURT: Overruled.

5 BY MS. SINGER:

6 Q. Mr. Rannazzisi, did DEA bring additional actions
7 against AmerisourceBergen during your tenure as Deputy
8 Assistant Administrator?

9 A. I don't recall any additional actions against
10 AmerisourceBergen.

11 Q. And was the fact that DEA, to your knowledge, did not
12 initiate an enforcement action against AmerisourceBergen a
13 sign that, that you had found, or that DEA had found
14 AmerisourceBergen's compliance with the Controlled
15 Substances Act?

16 A. No. The fact that there was no enforcement action
17 doesn't mean they were compliant, doesn't mean they weren't
18 compliant. We just didn't have -- during our, our
19 investigations, they did not come up.

20 Q. Okay. Let's turn to P-08873, please.

21 MS. SINGER: Your Honor, may I approach?

22 BY MS. SINGER:

23 Q. Mr. Rannazzisi, do you recognize P-08873? You
24 might want to turn back -- I'm sorry. Let me direct you
25 to a page. It's a composite exhibit. And I should note

1 that it's already been admitted.

2 Let's start -- sorry. Let's start at Bates Number 49,
3 please.

4 MS. WICHT: I'm sorry. Is there a Bates number?

5 MS. SINGER: I'm sorry, the P number.

6 MS. WICHT: P number. Thank you.

7 BY MS. SINGER:

8 **Q.** Mr. Rannazzisi, have you found that page?

9 **A.** Yes, I have.

10 **Q.** Okay. Why don't you turn one more page. Do you
11 recognize this document?

12 **A.** Yes, I do.

13 **Q.** And what do you recognize it to be?

14 **A.** An Order to Show Cause and Immediate Suspension Order.

15 **Q.** I'm sorry, I didn't hear the last part.

16 **A.** An Order to Show Cause and Immediate Suspension Order.

17 **Q.** Against who?

18 **A.** Against Cardinal Health, their Auburn facility.

19 MS. WICHT: Your Honor, objection to this line of
20 questioning with this witness. The Court may recall that
21 prior to trial, the issue of the scope of Mr. Rannazzisi's
22 testimony was addressed.

23 And the Court ruled that Mr. Rannazzisi's testimony
24 would be limited to the scope of his deposition taken in
25 Track 1 of the MDL. And that's at Docket 1260.

1 Mr. Rannazzisi was not questioned in his MDL deposition
2 about the 2008 enforcement action against Cardinal Health at
3 all by either party, either side.

4 And, so, we object to questioning of him on this
5 general subject matter here.

6 THE COURT: How about that, Ms. Singer?

7 MS. SINGER: So two points on this, Your Honor.

8 All of these documents were provided to defendants
9 prior to Mr. Rannazzisi's testimony on Sunday.

10 I'll note that Cardinal did not object at that time to
11 testimony about this document. And that's particularly
12 difficult in this instance where, you know, it leaves us
13 unable on the, on the fly to provide you with specific
14 references.

15 However, that said, I would note that Mr. Rannazzisi
16 was questioned extensively by both parties about DEA
17 enforcement action against all of the defendants.

18 THE COURT: Is that right, Ms. Wicht?

19 MS. WICHT: He was questioned generally about DEA
20 enforcement actions. But, Your Honor, we've gone and looked
21 at the transcript and he specifically was not questioned
22 about the 2008 enforcement action against Cardinal Health.

23 With respect to the objections, I would note that when
24 we transmitted the objections to all of the identified
25 Rannazzisi exhibits, the defendants also expressly reserved

1 their right to object to testimony or the use of exhibits in
2 a manner that exceeds the scope of the Court's order that I
3 referenced which is docket entry 1260, limiting him to the
4 scope of his Track 1 MDL deposition.

5 MR. ACKERMAN: Your Honor, may I be permitted to
6 address this?

7 MS. SINGER: I think he's asking for dispensation,
8 Your Honor, to this particular point.

9 THE COURT: Why don't you go talk to him, Ms.
10 Singer.

11 MR. ACKERMAN: All right.

12 (Ms. Singer and Mr. Ackerman conferred off the record
13 after which the following occurred:)

14 MS. SINGER: So, Your Honor, without engaging in
15 hearsay, you will understand where this is coming from. But
16 that said, I would note that in the objections that
17 defendants provided, Cardinal offered an outside of scope
18 objection for other documents, but not this one.

19 And particularly where we're tying testimony to
20 particular cites, it seems very unfair to then walk into
21 court on a general reservation and ask us to explain where
22 something was referenced.

23 I can assure the Court that over the two days of
24 testimony, Mr. Rannazzisi was questioned extensively on, on,
25 on enforcement actions, including the 2012 action which

1 incorporated this specific Order to Show Cause as an
2 attachment.

3 I would note that Cardinal also offered specific
4 objections on this document not related --

5 THE COURT: Well, let me give Ms. Wicht the last
6 word here.

7 MS. WICHT: Your Honor, just a couple of points.

8 We did object with respect to scope of this document as
9 to geographic scope and also as to personal knowledge for
10 the witness.

11 And then the second thing I would note, Your Honor, is
12 simply that it's a court order. It's an order that you've
13 already issued, Your Honor, saying that he's restricted to
14 the scope of that deposition. So I don't, I don't --

15 THE COURT: Well, they're saying that that's not
16 within the -- this is not within the Court's ruling on
17 scope.

18 MS. WICHT: Well, I would, I would invite the
19 plaintiffs to identify for us where in the Track 1 MDL
20 deposition Mr. Rannazzisi testified about the 2008
21 enforcement action against Cardinal Health because he did
22 not. There was a question -- there was --

23 THE COURT: Well, I'm going to cut this short and
24 overrule the objection and let, let him testify.

25 BY MS. SINGER:

1 **Q.** All right. Mr. Rannazzisi, I think you testified
2 that you were familiar with the first immediate -- the
3 first Order to Show Cause and Immediate Suspension Order
4 against the Auburn facility; is that correct?

5 **A.** Yes.

6 **Q.** Okay. Let's turn the page, then, to the next Order to
7 Show Cause at P Number 54 and 55. Do you recognize this
8 document?

9 **A.** Yes.

10 **Q.** And what do you recognize that document as?

11 **A.** An Order to Show Cause and Immediate Suspension Order.

12 **Q.** Against whom?

13 **A.** Cardinal Health Lakeland.

14 **Q.** And where is the Lakeland distribution center?

15 **A.** In Florida.

16 **Q.** And what is the date of this Order to Show Cause and
17 Immediate Suspension Order?

18 **A.** December 5th, 2007.

19 **Q.** Okay. And let's turn to P Number, please, 61. Are you
20 familiar with this document?

21 **A.** Yes.

22 **Q.** And what is it?

23 **A.** Another Order to Show Cause and Immediate Suspension
24 Order.

25 **Q.** And which, which defendant and facility does this one

1 relate to?

2 **A.** Cardinal Health in Swedesboro, New Jersey.

3 **Q.** And what is the date of this Order to Show Cause and
4 Immediate Suspension Order?

5 **A.** December 7th, 2007.

6 **Q.** All right. And then let's turn to P Number 67. Do you
7 recognize this document?

8 **A.** Yes.

9 **Q.** And what do you recognize this document to be?

10 **A.** This is a straight Order to Show Cause.

11 **Q.** And what does this relate to?

12 **A.** Cardinal Health Facility in Stafford, Texas.

13 **Q.** And what is the date of this Order to Show Cause?

14 **A.** January 30th, 2008.

15 **Q.** Okay. And were you involved in signing off on each of
16 these enforcement actions against Cardinal?

17 **A.** Yes. They -- I was generally the last signature or
18 initial before it went to the administrator, or deputy
19 administrator except for the last one I signed. I'm sure I
20 signed that because it's an Order to Show Cause. Yes, I did
21 sign that.

22 **Q.** And what had DEA found with respect to Cardinal's
23 dis- -- Cardinal's distribution of controlled substances?

24 MS. WICHT: Your Honor, I'll object to the
25 characterization of "found" as alleged. These are

1 allegations.

2 MS. SINGER: I think they reflect, Your Honor,
3 DEA's --

4 THE COURT: Overrule the objection. Go ahead and
5 answer.

6 BY MS. SINGER:

7 **Q.** Just speak in general, Mr. Rannazzisi.

8 **A.** Just generally that, again, they were not identifying,
9 reporting, or stopping large volumes of, of controlled
10 substances, hydrocodone, going downstream to pharmacies.

11 **Q.** And you mentioned hydrocodone. Does the failures reach
12 opioids beyond hydrocodone, if you know?

13 **A.** I don't, I don't remember, but hydrocodone for sure.

14 **Q.** Now, was there ultimately a Settlement Agreement
15 between DEA and Cardinal?

16 **A.** Yes, I believe there was.

17 **Q.** And were you -- let's turn to Page 34 of the P Number,
18 please.

19 MS. WICHT: Your Honor, just while we're finding
20 that page, may I assume -- I understand the Court has
21 overruled the objection. May I assume a continuing
22 objection on this line of questioning has been preserved?

23 THE COURT: Yes, you may.

24 MS. WICHT: Thank you, Your Honor.

25 BY MS. SINGER:

1 Q. Mr. Rannazzisi, are you on that P Number 34?

2 A. Yes.

3 Q. Okay. Do you recognize this document?

4 A. Yes. It's a Settlement and Release Agreement.

5 Q. And who is that Settlement Agreement between?

6 A. Cardinal Health and DEA.

7 Q. And does this Settlement Agreement resolve the Orders
8 to Show Cause and Immediate Suspension Orders that you just
9 went through?

10 A. Yes, they do.

11 Q. And, by the way, had you -- were you familiar with this
12 Settlement Agreement in your time at DEA?

13 A. Yes.

14 Q. Okay. Let's turn to Page P Number 35, Paragraph 3,
15 "Covered Conduct." And can you again read that paragraph,
16 please?

17 A. "Covered Conduct. For purposes of this agreement,
18 covered conduct shall mean the following: The conduct
19 alleged in the Orders to Show Cause, Appendices B through E,
20 the alleged failure of Cardinal to maintain adequate
21 controls against the diversion of controlled substances, on
22 or prior to September 30, 2008, at all distribution
23 facilities listed in Appendix A operated, owned, or
24 controlled by it."

25 Q. Let's stop there for a second and just flip, if we

1 could, to Appendix A which I believe is at Page 46.

2 Do you recognize this Appendix A of the distribution
3 centers covered by this Settlement Agreement?

4 **A.** Yes.

5 **Q.** All right. I'm sorry. If you could flip back to what
6 you were reading. I think you were at Paragraph B.

7 **A.** "The conduct described in Appendix F, Paragraph 8 to
8 this agreement; and the alleged failure of Cardinal to
9 detect and report suspicious orders of controlled substances
10 as required by 21 C.F.R. 1301.74(b) on or before
11 September 30, 2008."

12 **Q.** And had, had you concluded that the distribution of
13 controlled substances by Cardinal's distribution centers
14 represented an imminent threat to public safety?

15 MS. WICHT: Objection, calls for a legal
16 conclusion.

17 THE COURT: Overruled.

18 THE WITNESS: The Orders to Show Cause and
19 Immediate Suspension Orders when I reviewed them, I felt --
20 I wouldn't have initialed off and moved them on if I didn't
21 feel that was the case, however, again, with the caveat that
22 only the deputy administrator can make that call.

23 BY MS. SINGER:

24 **Q.** And had, had you found that the conduct laid out in
25 these Orders to Show Cause and Immediate Suspension

1 Orders was systemic and nationwide?

2 MS. WICHT: Objection, foundation.

3 THE COURT: Overruled.

4 THE WITNESS: Yes, based on the conduct that
5 was -- alleged conduct that was in the Orders to Show Cause,
6 I believed that it was a systemic breakdown nationwide.

7 BY MS. SINGER:

8 **Q.** Did each of the Immediate Suspension Orders and
9 Orders to Show Cause and Settlement Agreements that
10 we've talked about this morning cover conduct that DEA
11 had warned defendants about in the distributor
12 initiative briefings?

13 **A.** Yes.

14 **Q.** And does each of these Settlement Agreements -- you
15 said you're familiar with them -- require defendants to
16 follow the law?

17 **A.** Yes, that was a requirement that we -- that was a
18 requirement, yes.

19 **Q.** And did it require each -- did these Settlement
20 Agreements require each of these defendants to report and
21 not ship suspicious orders?

22 **A.** Yes, I believe each one of them has that provision in
23 it, yes.

24 **Q.** And did any of the defendants indicate at the time that
25 they entered into these Settlement Agreements that they did

1 not know what was required of them?

2 MS. WICHT: Objection, hearsay, foundation.

3 MR. SCHMIDT: Yeah, and, and literally asking us
4 about what we didn't say is hearsay and foundation and it
5 couldn't be an admission.

6 THE COURT: Well, the question was did any of the
7 defendants indicate at the time they entered into these
8 Settlement Agreements that they did not know what was
9 required of them. We don't know what his answer is, so I
10 don't know whether it's hearsay or not. Overruled.

11 THE WITNESS: Nobody indicated to me. None of the
12 defendants indicated to me that they didn't understand the
13 provisions of the Settlement Agreement.

14 BY MS. SINGER:

15 **Q.** And if they had made that represen- -- expressed
16 that concern to your staff, would you expect to have
17 been told of that?

18 **A.** Oh, absolutely.

19 **Q.** And --

20 **A.** But I think that if those reservations were expressed,
21 there wouldn't have been signatures on the Settlement
22 Agreement.

23 **Q.** Did DEA have occasion to turn back to enforcement
24 activities and investigation of these defendants after these
25 Settlement Agreements?

1 **A.** There -- well, at least two of the defendants, yes.

2 **Q.** Okay. And when was that?

3 **A.** It was later on after 2010, I believe. Yeah, we
4 started around 2010, yes.

5 **Q.** Okay. And what, what turned your attention back to
6 those defendants?

7 **A.** The same, the same conduct; large quantities of
8 controlled substances going downstream to pharmacies without
9 any appropriate review, due diligence, reporting. They were
10 just shipping.

11 THE COURT: Which two of the defendants are we
12 talking about?

13 THE WITNESS: I'm sorry, Your Honor. It would
14 have been McKesson and Cardinal.

15 THE COURT: Okay.

16 BY MS. SINGER:

17 **Q.** All right. Let's turn to P-00298.

18 MS. SINGER: May I approach, Your Honor?

19 BY MS. SINGER:

20 **Q.** All right. Before asking you about this particular
21 document, Mr. Rannazzisi, are you aware of whether your
22 senior staff met with staff of the Health
23 Distributors -- HDMA in 2011?

24 **A.** Oh, I'm, I'm sure they, they met multiple times
25 including 2011.

1 **Q.** Okay. And would you typically talk with your staff
2 before they participated in those meetings?

3 **A.** Sometimes I would. Sometimes I wouldn't. But it just
4 depends on the nature of the meeting, yes.

5 **Q.** And were you briefed by your staff after those meetings
6 about what had happened?

7 **A.** Yes, I would always be briefed on, on industry
8 meetings, yes.

9 **Q.** And I want to ask you to turn -- I'd like you to turn
10 to -- I'm sorry. I need to catch up with myself.

11 MS. SINGER: May I take a moment, Your Honor?

12 THE COURT: Yes.

13 (Pause)

14 MS. SINGER: I've got it. I'm sorry.

15 All right. We're going to come back to this document.
16 I certainly don't want to waste everyone's time.

17 BY MS. SINGER:

18 **Q.** All right. Let's move to the next. Let's turn to
19 P-08873, please. Okay. It's the large packet of
20 Cardinal documents you just were looking at. So we're
21 going to turn back to that. Do you have it back in
22 front of you?

23 **A.** Yes.

24 **Q.** Okay. Let's turn to Bates -- P number, I'm sorry, 27.

25 **A.** Okay.

1 Q. All right. Turn now to the next page, P-28. Do you
2 recognize this document, Mr. Rannazzisi?

3 A. Yes, I do.

4 Q. And what do you recognize this document to be?

5 A. It's an Order to Show Cause and Immediate Suspension
6 Order, the Cardinal facility in Lakeland, Florida.

7 Q. And were you involved in the decision to recommend --

8 THE COURT: Just a minute, Ms. Singer.

9 Ms. Wicht.

10 MS. WICHT: I'm sorry, Your Honor. I'm trying to
11 find my notes. My -- I believe that this particular
12 document was previously excluded by the Court on May 20th.
13 This was introduced and Your Honor sustained the objection
14 to the Lakeland warrant.

15 MS. SINGER: Your Honor, if I may, there has been
16 additional testimony by this witness that it was DEA's
17 knowledge and his knowledge in particular that these systems
18 were nationwide.

19 And I think on that basis we'd ask that Mr. Rannazzisi
20 be permitted to testify about what he observed and, in
21 particular, to lay a foundation to allow us to move to admit
22 this document.

23 THE COURT: The clerk has it down as admitted, Ms.
24 Wicht.

25 MS. WICHT: Your Honor, I have -- our records show

1 that the document, that 8873 was admitted, but that the 2011
2 Lakeland warrant contained within it, the objection was
3 sustained as to that.

4 MS. SINGER: And, Your Honor, on our end we show
5 the entire document to have been admitted.

6 THE COURT: Well, I don't remember. We don't
7 remember. And the only way to find out for sure is to go
8 back and look at the transcript.

9 MS. WICHT: Understood, Your Honor. And I
10 apologize for not having that for the Court this morning.
11 We will take a look at that and come back to you.

12 THE COURT: Well, I'm going to conditionally admit
13 it so we can get on with this. And if you can show me that
14 it shouldn't be admitted, Ms. Wicht, I'll make a
15 determination not to consider it.

16 Mr. Farrell.

17 MR. FARRELL: Yes. I believe that this is a
18 composite exhibit and I believe Ms. Wicht was right that you
19 allowed certain aspects of it and, and there was a
20 foundation problem on this document. And I would suspect
21 that's why Ms. Singer is attempting to cure that with this
22 witness.

23 MS. WICHT: We don't object to proceeding
24 conditionally as Your Honor laid out and sorting that out,
25 if need be, later on. Thank you.

1 THE COURT: All right.

2 BY MS. SINGER:

3 Q. All right. So, Mr. Rannazzisi, I think you
4 established that you recognized this document. Did DEA
5 issue this Order to Show Cause following a legally
6 authorized investigation?

7 A. Yes, it did.

8 Q. And does this document set forth the findings from that
9 investigation?

10 A. Yes, it does.

11 MS. SINGER: So, Your Honor, to the extent that
12 this hasn't been admitted, I would move its admission.

13 THE COURT: Is there any objection now, Ms. Wicht?

14 MS. WICHT: In addition to what we've already
15 discussed, Your Honor, we would object on the basis of
16 geographic scope. This document relates to four particular
17 pharmacies located in Florida.

18 THE COURT: Well, I've dealt with the geographic
19 scope objections before and I think the theory is that there
20 is a systemic failure that transcended the -- pretty much
21 the entire operation which would have encompassed
22 Cabell/Huntington and -- Cabell/Huntington.

23 So I'm going to overrule the geographic scope
24 objection. I think that that goes to the weight rather than
25 the admissibility. And we'll proceed conditionally with

1 regard to the other objections.

2 BY MS. SINGER:

3 **Q.** Now, as with, as with other Orders to Show Cause
4 and Immediate Suspension Orders, did you approve and
5 recommend this Order to Show Cause and Immediate
6 Suspension Order to the deputy administrator?

7 **A.** Again, I reviewed, like the others, the Immediate
8 Suspension -- the Order to Show Cause and Immediate
9 Suspension Order. I gave my initial approval and sent it
10 up. Only the deputy administrator can make a decision on
11 imminent threat.

12 **Q.** And can you read Paragraph 5 of this Order to Show
13 Cause and Immediate Suspension Order?

14 **A.** "Notwithstanding the large quantities of controlled
15 substances ordered by Cardinal's top retail pharmacy
16 customers, Cardinal failed to conduct meaningful due
17 diligence to ensure that the controlled substances were not
18 diverted into other than legitimate channels, including
19 Cardinal's failure to conduct due diligence of its retail
20 pharmacy chain customers. Furthermore, Cardinal failed to
21 detect and report suspicious orders of oxycodone products by
22 its pharmacy customers, as required by 21 C.F.R. 1301.74(b).
23 In addition, Cardinal's conduct described herein violated
24 the provisions of the administrative memorandum of
25 agreement."

1 **Q.** And does that accurately reflect DEA's assessment of
2 Cardinal's distribution -- I'm sorry -- DEA's findings in
3 this investigation?

4 **A.** Yes.

5 **Q.** And do you believe that the failures described here
6 were limited to these customers of the Cardinal -- of that
7 Cardinal distribution center?

8 MS. WICHT: Objection, foundation.

9 THE COURT: Overruled.

10 THE WITNESS: Could you repeat the question one
11 more time? I didn't catch it.

12 BY MS. SINGER:

13 **Q.** Did, did, did the paragraph you just read
14 accurately reflect DEA's -- I'm sorry. That's two
15 questions ago.

16 Were the failures described here in Paragraph 5 that
17 you just read limited to the four Cardinal customers at this
18 distribution center, or did you believe that they were
19 systemic failings as well?

20 MS. WICHT: I'll object only to clarify that we're
21 speaking within the scope of his own personal individual
22 knowledge.

23 THE COURT: Well, overruled, if he knows.

24 THE WITNESS: Well, I believe that because there
25 was, again, another systemic failure that was happening

1 elsewhere as well.

2 BY MS. SINGER:

3 **Q.** Now, had DEA communicated with Cardinal prior to
4 issuing this Immediate Suspension Order about the issues
5 raised in the Order to Show Cause?

6 **A.** Yes, I believe there were communications.

7 **Q.** And do you recall the details of those communications,
8 how many, with whom, et cetera?

9 **A.** I believe the communications occurred at the division
10 level with DPM and the group supervisor as well as
11 headquarters staff.

12 **Q.** And do you recall whether -- roughly how many
13 communications there were?

14 **A.** I don't recall.

15 **Q.** Is there a document that might refresh your
16 recollection?

17 **A.** I'm sure there's a document that, that has the content
18 of the discussions that, between -- yes, there should be a
19 document.

20 **Q.** And do you recall, did Cardinal challenge this
21 immediate -- this Order to Show Cause and Immediate
22 Suspension Order in Federal Court in the District of
23 Columbia?

24 **A.** Oh, yes, yes, they did.

25 **Q.** And do you recall whether you submitted a declaration

1 in connection with that action?

2 **A.** I did submit a declaration.

3 **Q.** And do you know whether that declaration describes the
4 details of DEA's investigation and its interactions with
5 Cardinal prior to the Order to Show Cause and Immediate
6 Suspension Order?

7 **A.** Yes, it does.

8 **Q.** And do you think looking at that declaration would
9 refresh your recollection as to those communications?

10 **A.** Yes, it would.

11 MS. SINGER: Can you give me please P-00013.

12 P-09399.

13 May I approach, Your Honor?

14 BY MS. SINGER:

15 **Q.** So, Mr. Rannazzisi, just reading to yourself and
16 not aloud, I direct you to Paragraph 73.

17 **A.** Paragraph 73?

18 **Q.** I hope so.

19 THE COURT: Does that refresh your recollection?

20 THE WITNESS: Paragraph 73 does not. I'll
21 continue to look. I'm sure it's in here, though. I think
22 it's in Paragraph 59. Try Paragraph 59.

23 BY MS. SINGER:

24 **Q.** Sorry about that. All right.

25 Having looked at that paragraph, Mr. Rannazzisi, does

1 that refresh your recollection as to communications or
2 interactions between DEA and Cardinal Health in advance of
3 the Order to Show Cause?

4 **A.** Yes.

5 **Q.** Okay. And can you now testify as to the details of
6 those communications and interactions?

7 THE COURT: Just a minute. We've got an objection
8 here.

9 MS. WICHT: Well, I'm not sure -- maybe Ms. Singer
10 hasn't gotten there yet but, obviously, the document should
11 be removed from the witness before he testifies.

12 THE COURT: Absolutely.

13 You need to read it, Mr. Rannazzisi, and say whether or
14 not it refreshes your recollection. If it does, then you
15 have to testify from memory rather than reading into the
16 record the declaration.

17 THE WITNESS: Yes. I just -- there were two
18 sections, so I just wanted to read both sections.

19 THE COURT: Well, go ahead and read them.

20 THE WITNESS: Thank you, sir.

21 MR. WESTFALL: I just want to make sure if the
22 question posed is the communication between -- between the
23 DEA and Cardinal or communications that he had with other
24 people within the agency.

25 MS. SINGER: I think I've asked for his

1 interactions -- the DEA's interactions with Cardinal.

2 MR. WESTFALL: Okay.

3 (Pause)

4 THE WITNESS: Okay.

5 THE COURT: You can retrieve the document and
6 question him about it, Ms. Singer.

7 BY MS. SINGER:

8 Q. So, Mr. Rannazzisi, having reviewed your
9 declaration, does that refresh your recollection as to
10 the interactions between DEA and Cardinal in advance of
11 the Order to Show Cause and Immediate Suspension Order?

12 A. Yes.

13 Q. And what were those interactions?

14 A. There was an inspection done at the Peabody facility in
15 Massachusetts. And during that inspection, DEA found that
16 there was no due diligence being conducted on chain drug
17 stores.

18 The, the lead investigator, inspector was in contact
19 with the Cardinal, the Cardinal people and told them, "You
20 must do due diligence."

21 MS. WICHT: Objection, hearsay. I'm sorry.

22 THE COURT: How does it come in?

23 MS. SINGER: Your Honor, I believe that the -- the
24 hearsay exception is that it's being offered to provide
25 notice to the defendant about the guidance that DEA was

1 providing about what was required of it.

2 THE COURT: Well, it might come in as an
3 admission, but not hearsay. I'll overrule the objection and
4 see what he says.

5 THE WITNESS: They must do due diligence on chain
6 drug stores, which -- and they were put on notice of that.

7 Moving ahead to the Order to Show Cause, if you notice
8 in the Order to Show Cause there were several -- two
9 particular pharmacies, 5195 and 219 in Sanford, Florida.
10 And both of those pharmacies were chain drug stores. And
11 the volumes going to those pharmacies were outrageous.

12 And they didn't do due diligence that was told they
13 must do by I think at that point in time it was Inspector
14 Arpaio, Mike Arpaio.

15 Q. And the failures to do due diligence that you have just
16 described, were those the same types of failures, if you
17 know, that DEA had observed in 2008?

18 MS. WICHT: Objection, foundation.

19 THE COURT: Overruled.

20 THE WITNESS: Due diligence is due diligence. So,
21 yes, it's the same due diligence problems. You're not,
22 you're not reviewing the customers' orders. You're not
23 comparing those orders. You're just not doing what's
24 appropriate to determine what's suspicious and what's not,
25 and then stop those orders from going downstream.

1 BY MS. SINGER:

2 Q. In 2012 -- are you aware that Cardinal entered into
3 a second Settlement Agreement with the DEA in 2012?

4 A. Yes.

5 Q. Okay. We're going to turn back to that big set of
6 documents at 208873. We're going to go to P Number 15. Do
7 you have that page in front of you?

8 A. Yes, I do.

9 Q. Okay. And have you seen that -- I'm sorry. What is
10 that document?

11 A. It's an Administrative Memorandum of Agreement.

12 Q. Okay. And is that the Settlement Agreement that
13 resolved the 2012 Order to Show Cause and Immediate
14 Suspension Order?

15 A. Yes.

16 Q. And had you seen this Settlement Agreement while you
17 were at DEA?

18 A. Yes.

19 Q. And do you know whether this Settlement Agreement
20 included enhanced compliance procedures that Cardinal agreed
21 to undertake, including with respect to chain pharmacies?

22 A. I believe that was in the agreement, yes.

23 Q. All right. And we can put that aside. I want to try
24 again with the document that I was struggling with before,
25 P-00298. Do you have that in front of you, Mr. Rannazzisi?

1 **A.** Yes, I do.

2 **Q.** Okay. I had asked you previously about whether you
3 were aware of staff -- meetings between DEA and the HDMA.
4 Do you recall that testimony?

5 **A.** Yes.

6 **Q.** And are you aware that during 2011 and 2012 DEA staff
7 met with the HDMA?

8 **A.** Yes, I am.

9 **Q.** And what is the HDMA?

10 **A.** Well, the HDMA, the Healthcare Distribution
11 Management --

12 **Q.** Can you get closer to the mic?

13 **A.** The Healthcare Distribution Management Association. I
14 think they're the had now.

15 **Q.** And do you know what the had or HDMA is?

16 **A.** They're an advocacy organization for the distributors.

17 **Q.** And did you know at the time at the DEA whether these
18 defendants were members of the HDMA?

19 **A.** Yes, they were all -- the defendants were all members
20 of the HDMA.

21 **Q.** And do you know whether they served a leadership
22 position with the HDMA?

23 **A.** I believe they were all on the executive board at one
24 time or another, yes.

25 **Q.** All right. And I just want to ask you to turn to P

1 Number 37 in the document that I've shown you.

2 **A.** Okay.

3 MS. WICHT: Your Honor, I'm sorry. I'm going to
4 lodge an objection to the use of this document with this
5 witness. There's been no indication that he's seen it
6 before. It recites on its face that it's an HDMA members
7 only document not for external circulation. I don't think
8 that the witness can consult it as he's testifying to inform
9 his answers.

10 MS. SINGER: So, Your Honor, if I may, these
11 minutes, or this document recounts a meeting between DEA and
12 the HDMA at which one of Mr. Rannazzisi's staff conveyed the
13 position of the DEA. And I want to ask Mr. Rannazzisi
14 whether he agrees with that statement. I think Mr. Hester
15 did the same thing with Dr. O'Connell yesterday.

16 MR. SCHMIDT: Your Honor, we'll object to
17 foundation if he doesn't have a basis to give specific
18 foundation testimony as to this document. Just reading a
19 statement from a document he's never seen seems improper.
20 That makes him an expert.

21 THE COURT: Yeah. I think you have to lay a
22 foundation, Ms. Singer, if you want to ask him about it.

23 BY MS. SINGER:

24 **Q.** So, so, Mr. Rannazzisi, are you familiar with a
25 meeting that took place in December of 2011 between DEA

1 and HDMA?

2 **A.** Yes.

3 **Q.** And do you know which DEA staff were present at that
4 meeting?

5 **A.** My executive assistant was present and my staff.

6 **Q.** And what was the name of your executive assistant at
7 that time?

8 **A.** Gary Boggs.

9 **Q.** Okay. And prior to that meeting did you have a
10 conversation with Mr. Boggs about, about what would happen
11 at that meeting?

12 **A.** Yes. We would discuss those meetings. When he's
13 attending in my place or as my representative, we would
14 always discuss, yes.

15 **Q.** And did you --

16 MR. SCHMIDT: No objection.

17 BY MS. SINGER:

18 **Q.** Did you talk with Mr. Boggs about the, about any
19 message that the DEA might convey, that he might
20 convey --

21 MR. SCHMIDT: Now --

22 BY MS. SINGER:

23 **Q.** -- on your behalf at that meeting?

24 MR. SCHMIDT: Now I'll object on hearsay.

25 THE WITNESS: We wanted them --

1 THE COURT: Just a minute.

2 I'll sustain the objection on the hearsay ground, Ms.
3 Singer.

4 MS. SINGER: So, Your Honor, I think this
5 testimony goes to his supervision of his direct report who
6 he has directed to convey a message to HDMA which goes to
7 the non-hearsay purpose of what DEA communicated to these
8 defendants.

9 THE COURT: Well, what about that, Mr. Schmidt?

10 MR. SCHMIDT: I think his -- he doesn't have a
11 basis. He can, I guess, say, "Did you intend for Mr. Boggs
12 to do something?" But to then say it was actually done,
13 that would be hearsay.

14 And I think that this is all a setup to try to have him
15 testify about not what Mr. Boggs said because that's not
16 what these slides are, but about what HDMA said, which is
17 what these slides are.

18 THE COURT: Well, what DEA communicated to these
19 defendants is hearsay if he is the witness testifying about
20 it and he wasn't there. Isn't that right?

21 MS. SINGER: So, Your Honor, I think it's not
22 hearsay because it goes to the notice question. This was a
23 communication by DEA to express the view of the regulator
24 about the regulated entity, these defendants' noncompliance
25 with the law.

1 MR. SCHMIDT: That argument would apply if he were
2 the one that directly made the communication. But there's
3 hearsay within hearsay if he's purporting to say that
4 Mr. Boggs actually said that.

5 THE COURT: I'll sustain the objection, Ms.
6 Singer.

7 MS. SINGER: All right.

8 BY MS. SINGER:

9 Q. Do you know, Mr. Rannazzisi, -- you can put the
10 document aside -- what message was delivered by DEA at
11 this meeting?

12 A. Yes.

13 Q. And what was that message?

14 MR. SCHMIDT: Same objection, Your Honor.

15 THE COURT: Yeah. You need to show how he knows.
16 And if he knows because of what somebody told him, it's
17 hearsay.

18 BY MS. SINGER:

19 Q. How do you know what message was conveyed at that
20 meeting?

21 A. Because they were conveying a message that I wanted
22 them to convey at the time.

23 Q. And how do you know that, Mr. Rannazzisi?

24 A. Because I told them what to say.

25 Q. And this was within the scope of your authority and

1 their responsibility?

2 **A.** Yes.

3 MR. SCHMIDT: I think the witness is very artfully
4 not answering the question, which is someone told him
5 something about what was said. If no one told him and he
6 doesn't know, he has no foundation. If someone told him,
7 it's hearsay.

8 THE COURT: I'll sustain the objection.

9 MS. SINGER: I'll move on.

10 BY MS. SINGER:

11 **Q.** All right. Mr. Rannazzisi, I want to return very
12 briefly to a subject we discussed yesterday. But I
13 think when we recessed for the day, I didn't take the
14 time to finish the conversation.

15 To your knowledge, as Deputy Assistant Administrator,
16 prior to the distributor initiative meetings that we talked
17 about yesterday, were these defendants reporting suspicious
18 orders to DEA?

19 MR. SCHMIDT: Objection, calls for a legal
20 conclusion --

21 THE COURT: Overruled.

22 MR. SCHMIDT: -- and asked and answered.

23 THE COURT: Mr. Nicholas.

24 MR. NICHOLAS: And there's a lack of personal
25 knowledge.

1 THE COURT: Ms. Wicht.

2 MS. WICHT: Foundation, Your Honor.

3 THE COURT: Overruled.

4 Go ahead, Ms. Singer.

5 MS. SINGER: I'm sorry, Your Honor. Was that
6 overruled or sustained?

7 THE COURT: The objection is overruled. You can
8 ask him.

9 BY MS. SINGER:

10 **Q.** So were you aware, Mr. Rannazzisi, whether these
11 defendants were reporting suspicious orders to DEA prior
12 to the distributor initiative briefing?

13 **A.** No, that was the reason for the distributor initiative
14 meetings because we weren't getting suspicious orders. We
15 weren't getting the suspicious orders that basically
16 pinpointed or was a pointer system to potential diverters.
17 What we were getting was excessive purchase reports and, and
18 the like of the excessive purchase reports which are not
19 suspicious orders.

20 **Q.** And were those excessive purchase reports submitted at
21 the time an order was shipped or days or weeks after the
22 order was shipped?

23 **A.** I don't recall any suspicious -- any excessive order
24 report that was given to DEA at the time it was shipped.
25 And that, that wouldn't be a suspicious order. It would

1 have to resolve before they ship.

2 But even though most of the orders we received, those
3 excessive purchase orders were, you know, maybe weekly,
4 every two weeks, every month.

5 **Q.** And, so, does that mean in your experience, based on
6 your observations, that Cardinal, McKesson and
7 AmerisourceBergen were identifying orders as potentially
8 suspicious and then sending it to their customers anyway?

9 **A.** Well, if we weren't receiving suspicious orders and the
10 orders on a suspicious order didn't indicate that they were
11 stopping the shipment, then, yeah, my -- yes, then they
12 would be shipping those orders. Those excessive purchases
13 would be shipped.

14 **Q.** And do you know why these defendants were shipping
15 controlled substances that they suspected might be being
16 diverted?

17 MR. SCHMIDT: Objection, foundation, Your Honor.

18 MS. SINGER: If you know.

19 MR. SCHMIDT: How could he know?

20 MS. WICHT: The question incorporates a state of
21 mind of the defendant. I don't see how he possibly could
22 answer that, has foundation to answer that question.

23 MR. NICHOLAS: We join.

24 THE COURT: I'll sustain -- sustained.

25 BY MS. SINGER:

1 **Q.** Did you ever -- did you ever get any information or
2 did the defendants ever convey to you why they were
3 shipping suspicious -- shipping controlled substances
4 they thought might be diverted?

5 MR. SCHMIDT: Objection, characterization. That's
6 a misstatement of the record.

7 MR. NICHOLAS: Join.

8 MS. WICHT: Join in the objection as to
9 foundation.

10 THE COURT: Sustained. We don't have a time
11 period on this at all.

12 MS. SINGER: I'm sorry, Your Honor. I'll make
13 that clear. This is all prior to the distributor initiative
14 briefings in 2005.

15 BY MS. SINGER:

16 **Q.** So with that qualification, Mr. Rannazzisi, -- and
17 I'm certain that there will be an objection as well --
18 did you ever get any information as to why defendants
19 were shipping orders that they suspected might be
20 diverted?

21 MR. SCHMIDT: Objection. There's no foundation
22 for that question. The testimony from every company witness
23 has been contrary to that.

24 THE COURT: Well, the question was: Did you ever
25 get any information as to why defendants were shipping

1 orders that they suspected might be diverted?

2 I'm going to let him answer that question and then
3 we'll see where we go from there.

4 MR. WESTFALL: Your Honor, on behalf of the United
5 States we would object to the question inasmuch as his
6 answers are going to give a lot of attorney/client
7 privileged information or law enforcement privileged
8 information. He can't disclose that.

9 THE COURT: Well, I don't see -- I'm going to have
10 him answer it.

11 MR. SCHMIDT: And I'll also just note that there's
12 a foundation issue. He did not talk to us prior to the
13 distributor initiative.

14 MR. NICHOLAS: There's also -- forgive me, but
15 baked into the question is the assumption that the
16 distributors thought that particular orders might be
17 diverted. And there's been absolutely no foundation for
18 that at all.

19 It's sort of a -- he's building -- Ms. Singer is, is
20 layering in an assumption, you know, in the question which
21 is, which is -- for which there has been no foundation laid.

22 MR. SCHMIDT: That's a better way of saying what I
23 was trying to say.

24 THE COURT: Ms. Wicht.

25 MS. WICHT: I join in the objection, Your Honor.

1 THE COURT: Well, the question was, if I
2 understood it, was did he ever get any information that the
3 defendants were shipping orders that they believed to be
4 suspicious. And he can answer that question and then we'll
5 see where we go from there.

6 MR. SCHMIDT: And that's fine. That's different
7 than what he was asked which is likely to be diverted.

8 THE COURT: Okay. Can you answer that question,
9 Mr. Rannazzisi?

10 THE WITNESS: Your Honor, I apologize. I don't
11 remember the question.

12 MS. SINGER: Oh, no.

13 THE COURT: The question was, if I understood it,
14 did you ever get any information that the defendants were
15 shipping orders that they believed to be suspicious.

16 THE WITNESS: I cannot recall any information that
17 was specific that they were shipping orders that they knew
18 to be specific (verbatim) that I received.

19 THE COURT: Okay.

20 BY MS. SINGER:

21 **Q.** All right. And yesterday, Mr. Rannazzisi, I showed
22 you an Ingredient Limit Report. Do you recall that?

23 **A.** Yes.

24 **Q.** Okay. And do you still have it up there in front of
25 you?

1 **A.** Yes.

2 **Q.** Okay. And I just want to ask you briefly now, the ILR
3 report you have that's P-28091 is an example of an
4 Ingredient Limit Report. Is that right?

5 MS. WICHT: I'm sorry. Could you say that number
6 again, Ms. Singer? That's not the number that I have for
7 the exhibit.

8 MS. SINGER: Okay. I'm sorry.

9 MS. WICHT: I may be wrong.

10 MS. SINGER: It's -- I'm sorry, P-14288. Is that
11 the correct number?

12 MS. WICHT: That's what I have. Thank you.

13 BY MS. SINGER:

14 **Q.** Mr. Rannazzisi, is that what you have?

15 **A.** That's what I have.

16 **Q.** Okay. So P-14288, is that an example of an Ingredient
17 Limit Report that DEA received from Cardinal?

18 **A.** Yes.

19 **Q.** Okay.

20 MS. SINGER: And then can we see P-42747, please?

21 May I approach, Your Honor?

22 THE COURT: Yes.

23 MS. SINGER: And because this is a voluminous
24 exhibit, I think we only have five copies per the
25 stipulation.

1 BY MS. SINGER:

2 Q. And, Mr. Rannazzisi, do you recognize the type of
3 document that, that we've shown you in P-42747?

4 A. It's, it's just another monthly report of transactions.
5 That's all it is.

6 Q. And do you know which, which company, which defendant
7 that report is from?

8 A. McKesson.

9 Q. Okay. And let's also do P-28007, please.

10 MS. SINGER: May I approach again, Your Honor?

11 THE COURT: Yes.

12 BY MS. SINGER:

13 Q. And, Mr. Rannazzisi, do you recognize what type of
14 document that is?

15 A. This is an Excessive Purchase Report.

16 Q. And are each of these examples the kinds of excessive
17 purchase reports that DEA was receiving prior to the
18 distributor initiative briefings in 2005?

19 MR. SCHMIDT: Object to the characterization.

20 MS. WICHT: I'll object on the basis of
21 foundation.

22 THE COURT: Overruled.

23 THE WITNESS: Yes.

24 BY MS. SINGER:

25 Q. And how many orders are in -- let's take P-42747,

1 the McKesson report. Roughly how many transactions are
2 in that report?

3 **A.** A lot. I can't tell you how many transactions.

4 **Q.** Hundreds? More than that?

5 **A.** It looks that way.

6 **Q.** And would DEA receive these reports for different
7 distribution centers from each defendant?

8 **A.** Yeah, the reports would come from the distribution
9 centers.

10 **Q.** And I think you said you would receive them every
11 couple weeks or every month; is that right?

12 **A.** It depends --

13 MS. WICHT: I'm sorry. Could we have a
14 clarification on time period?

15 BY MS. SINGER:

16 **Q.** This is all prior to the distributor initiative
17 briefings?

18 **A.** Yes. It depends on the -- it depends on the
19 distributor. But, yeah, a month is generally what we would
20 see.

21 **Q.** And did these reports provide DEA with, with the
22 details or intelligence that allowed you to determine
23 whether these transactions were actually suspicious?

24 **A.** No.

25 MS. WICHT: Objection, foundation, vague.

1 THE COURT: Overruled.

2 THE WITNESS: No, they don't. It's just
3 transactions. It looks like transactions above a threshold.
4 That's basically it.

5 BY MS. SINGER:

6 Q. So did it give you information on why a distributor
7 thought DEA should be aware of any of those
8 transactions?

9 A. No, there's nothing, there's nothing in here that has
10 any explanation of why it would be deemed suspicious.

11 Q. And were these reports useful to DEA?

12 MR. SCHMIDT: Objection, foundation. I think he
13 can answer as to himself, not as to DEA.

14 THE COURT: Well, if he knows. I'll overrule the
15 objection.

16 You can answer if you can, Mr. Rannazzisi.

17 THE WITNESS: To me, no, these, these, these have
18 no value because all it is is reporting transactions over a
19 threshold. I don't know anything about any of these
20 pharmacies. I don't have an explanation of why this would
21 be deemed suspicious. They're not, they're not given to us
22 when discovered. It's just a monthly printout of
23 transactions, you know, above a certain threshold. So, no,
24 I -- no.

25 BY MS. SINGER:

1 **Q.** And when DEA received suspicious order reports as
2 opposed to excessive purchase reports, did DEA
3 investigate those reports?

4 **A.** Again --

5 MR. NICHOLAS: Objection. I think this goes back
6 to the debate we had yesterday. And I'm not sure exactly
7 where we landed, but I think since the witness is unable to
8 provide any, any specific information here, I would object
9 based on, on foundation and lack of ability to probe as to
10 whatever his answer might be.

11 MR. SCHMIDT: Join.

12 THE COURT: Well, the question was: When DEA
13 received suspicious order reports as opposed to excessive
14 purchase reports, did DEA investigate those reports?

15 I think that's a perfectly proper question and I'll
16 overrule the objection and you can answer it if you can, Mr.
17 Rannazzisi.

18 THE WITNESS: I know investigative -- I know
19 suspicious order reports were investigated. I know that. I
20 can't tell you every suspicious order report was ever -- you
21 know, every one that was ever submitted was investigated.
22 But I know they were investigated and I know that was the
23 protocol to investigate those suspicious order reports.

24 BY MS. SINGER:

25 **Q.** And did suspicious order reports sometimes lead to

1 an action being taken against a registrant?

2 **A.** Suspicious order reports, like I said before, are a
3 pointer system. So it would lead the investigators to, if
4 not open an investigation, assist in an on-going
5 investigation.

6 **Q.** Now, did DEA give these defendants feedback that the
7 excessive purchase reports that we just looked at weren't
8 helpful to DEA?

9 MR. SCHMIDT: Objection as to time frame, if we
10 could just specify the time frame.

11 BY MS. SINGER:

12 **Q.** This is all prior to the --

13 THE COURT: Overruled.

14 BY MS. SINGER:

15 **Q.** Okay. Go ahead and answer, please.

16 THE COURT: Well, the time -- have you put a time
17 frame on it?

18 MS. SINGER: I haven't, Your Honor.

19 BY MS. SINGER:

20 **Q.** At any point during your tenure at DEA, did DEA
21 tell defendants that these excessive purchase reports
22 weren't helpful?

23 **A.** Yes, during, during my tenure, we did, yes, absolutely.

24 MR. WESTFALL: Your Honor, just so it's clear on
25 the record, he's testifying from his own personal

1 recollection. I think that's what he's limited to because
2 he doesn't know everything about all aspects of the DEA.

3 MR. SCHMIDT: And I think what this goes to in my
4 objection was that did happen during the distributor
5 initiative. That's not a contested fact.

6 Our objection is any suggestion that it happened
7 before, that he raised issues about the format of the
8 reporting before.

9 And, actually, just so -- let me restate what I said.
10 They have raised -- Mr. Rannazzisi has raised the issue that
11 he gave us guidance on suspicious orders. It's contested
12 what that guidance was and whether it was details or not.

13 I don't think it's contested that there was no such
14 even attempted guidance certainly from Mr. Rannazzisi before
15 the distributor initiative.

16 MS. SINGER: Your Honor, if I may, --

17 THE COURT: Well, I'm going to let him answer.
18 Overruled. Go ahead.

19 THE WITNESS: During, during my tenure when I was
20 there from 2005 on -- I forgot -- I apologize. I forgot the
21 question.

22 BY MS. SINGER:

23 **Q.** Did you give feedback to defendants that excessive
24 purchase reports were not helpful to the DEA?

25 **A.** During my tenure, yes, I did.

1 **Q.** And did you tell them that these excessive purchase
2 reports weren't suspicious order reports?

3 **A.** Yes, I did.

4 MS. SINGER: Your Honor, I'm about to start the
5 next block of questions. I'm happy to go as far as I can
6 until noon. But just as a courtesy, I wanted to raise that.

7 THE COURT: Well, I have mixed feelings here.
8 I've got another hearing at noon, but I understand there's
9 going to be a big argument about us being behind in time.
10 So why don't you press on for a few more minutes.

11 MS. SINGER: Okay.

12 BY MS. SINGER:

13 **Q.** All right, Mr. Rannazzisi, we focused this morning
14 on enforcement actions. I want to turn back to
15 guidance, what we were just talking about.

16 Even during the Orders to Show Cause and Immediate
17 Suspension Orders you've talked about, did DEA continue to
18 provide guidance to distributors?

19 **A.** Yes.

20 **Q.** And did you, did you send distributors and other
21 registrants a series of letters about their obligations
22 under the Controlled Substances Act?

23 **A.** Yes, I did.

24 **Q.** And did you approve each of those letters?

25 **A.** Yes, I did.

1 Q. And why did you send the letters?

2 A. The letters were sent to, again, reiterate what the
3 registrants' responsibilities were under the, under the
4 Controlled Substances Act, but specifically to suspicious
5 order monitoring, identification of suspicious orders
6 reporting and shipment.

7 Q. And I want to turn first to P-00032, please.

8 MS. SINGER: May I approach, Your Honor?

9 And just for purposes of the record, each of these
10 letters has already been admitted.

11 MS. WICHT: Your Honor, just to clarify, I think
12 they've been limited -- they've been admitted for the
13 limited purpose of notice over our objection.

14 BY MS. SINGER:

15 Q. So, Mr. Rannazzisi, let's turn first to the second
16 page of this exhibit.

17 A. Yes.

18 Q. Actually, let's turn to the September 27th letter. Do
19 you recognize this document?

20 A. Yes, I do.

21 Q. Okay. And who was this -- and what is the document?

22 A. It's the first letter post distributor initiative that
23 reinforces both what was in the distributor initiative, and
24 it provides information concerning obligations under the
25 Controlled Substances Act relating to suspicious order

1 monitoring.

2 **Q.** And to whom was this letter sent?

3 **A.** It was sent to all distributors and manufacturers
4 because manufacturers have coincidental authority to
5 distribute.

6 **Q.** And let's turn to the second page of the letter, if you
7 would. It says distributors have a statutory
8 responsibility --

9 **A.** Did you say the second page?

10 **Q.** Yes. If you can look at the second sentence of the
11 second paragraph, can you read that, please?

12 **A.** "DEA recognizes that the overwhelming majority of
13 registered distributors act lawfully and take appropriate
14 measures to prevent diversion. Moreover, all registrants,
15 manufacturers, distributors, pharmacies, and practitioners,
16 share responsibility for maintaining appropriate safeguards
17 against diversion. Nonetheless, given the extent of
18 prescription drug abuse in the United States, along with the
19 dangerous and potentially lethal consequences of such abuse,
20 even just one distributor that uses its DEA registration to
21 facilitate diversion can cause enormous harm. Accordingly,
22 DEA will use its authority to revoke and suspend
23 registrations in appropriate cases."

24 **Q.** And does that reflect the guidance that you provided to
25 DEA registrants in this letter?

1 **A.** Yes.

2 **Q.** And then let's turn to the third paragraph from the
3 bottom, please. Can you read that as well and read it out
4 loud, please?

5 **A.** "Thus, in addition to reporting all suspicious orders,
6 a distributor has a statutory responsibility to exercise due
7 diligence to avoid filling suspicious orders that might be
8 diverted into other than legitimate medical, scientific, and
9 industrial channels. Failure to exercise such due diligence
10 could, as circumstances warrant, provide a statutory basis
11 for revocation or suspension of a distributor's
12 registration."

13 **Q.** And then the last paragraph I want to ask you to look
14 at is the next paragraph, and if you could read that first
15 sentence of that next paragraph out loud, please.

16 **A.** "In addition, distributors are required to file reports
17 of distributions of certain controlled substances to the DEA
18 ARCOS unit in the time and manner specified in the --"

19 **Q.** I think we're at a different place. I'm sorry. "In a
20 similar vein," the paragraph above.

21 **A.** I'm sorry.

22 "In a similar vein, given the requirement under Section
23 823(e) that a distributor maintain effective controls
24 against diversion, a distributor may not simply rely on the
25 fact that the person placing the suspicious order is a DEA

1 registrant and turn a blind eye to the suspicious
2 circumstances."

3 **Q.** Why don't you go ahead and finish out that paragraph,
4 if you would.

5 **A.** "Again, to maintain effective controls against
6 diversion as Section 823(e) requires, the distributor should
7 exercise due care in confirming the legitimacy of all orders
8 prior to filling."

9 **Q.** So why can't a distributor rely on the fact that DEA
10 has approved one of its customer's registrations or hasn't
11 revoked a registration?

12 **A.** DEA, when they register an entity, be it a doctor or
13 pharmacy, a distributor, we can't guarantee you that they're
14 going to conform with the law somewhere down the road. And,
15 in fact, we might not know that they're not conforming to
16 the law.

17 It's kind of like a, a driver's license, you know.
18 Just because you give somebody a driver's license doesn't
19 mean they're not going to speed. It's the same concept.

20 That's why suspicious orders are so important because
21 if, if a registrant goes off track and decides to, decides
22 to get involved in illegal activity, that will give us a
23 point, give us an idea of what they're doing and how they're
24 doing it and then we can proceed with the investigation.

25 **Q.** So let's turn to the third page of the letter, if you

1 would. Can you tell us generally what the third page of the
2 letter lays out?

3 **A.** It just, it just lays out what they should be looking
4 for when it comes to diversion in their customer base.

5 **Q.** Okay. And "they" in your response means who or what?

6 **A.** The -- well, the whole distributor population and the
7 manufacturers.

8 **Q.** And then I'd like to draw your attention to Paragraph
9 7. So can you read Paragraph 7, please, the Number 7?

10 **A.** Number 7?

11 **Q.** Uh-huh.

12 **A.** "Are one or more practitioners writing a
13 disproportionate share of the prescriptions for controlled
14 substances being filled by a pharmacy?"

15 **Q.** And why did DEA suggest that as one of the signs or a
16 question that a distributor should be asking?

17 MS. WICHT: Object to the characterization of
18 "should" which mischaracterizes the document which says that
19 distributors may wish to inquire.

20 MR. WESTFALL: Again, Your Honor, for the United
21 States, he can only testify as to matters which are not
22 privileged by attorney/client privilege or the deliberative
23 process privilege or law enforcement privilege. He can only
24 testify as to public information.

25 THE COURT: I'm going to overrule the objections

1 and allow him to answer that one. Why did DEA suggest as
2 one of the signs or questions that a -- you remember the
3 question.

4 THE WITNESS: Yes, Your Honor. Thank you.

5 That's a red flag that we, we look at, what we've seen
6 in cases. One pharmacy with -- you know, this wide range of
7 practitioners that are prescribing, prescribing all sorts of
8 drugs but only one or two of them prescribe the vast
9 majority of controlled substances, that's something that you
10 have to look at and address and resolve. And, you know,
11 it's just a major red flag.

12 BY MS. SINGER:

13 Q. And did this first Rannazzisi letter -- and I'm
14 going to call it the Rannazzisi letter if that's okay
15 with you. Did the first Rannazzisi letter reflect a new
16 interpretation of the Controlled Substances Act or new
17 guidance from the DEA?

18 A. No.

19 Q. Was it consistent, to your knowledge, with the guidance
20 DEA had provided to distributors in the past?

21 MS. WICHT: Objection, foundation.

22 THE COURT: Overruled.

23 THE WITNESS: Yes, it did.

24 BY MS. SINGER:

25 Q. And -- okay. Let's turn to P-19525, please.

1 THE COURT: Is this a good place to stop, Ms.
2 Singer?

3 MS. SINGER: It is, Your Honor.

4 THE COURT: Okay. Let's be in recess until 2:00.
5 Oh, yeah, we'll come back at 1:45, 1:45.

6 (Recess taken at 11:53 a.m.)

7 THE COURT: Mr. Majestro.

8 MR. MAJESTRO: Thank you, Your Honor. I
9 appreciate you coming back early to hear this, what we think
10 is a very important request.

11 As of yesterday, we had 20 -- we've had 21 days of
12 trial. We're into our 22nd day today and, as of yesterday,
13 there were 93 hours of testimony. Of that, defendants used
14 a little more than 39 hours, which is 42 percent of the
15 time, and plaintiffs used almost 54 hours, which is 57.8
16 percent of the time.

17 Now, while we have more time, that's not surprising.
18 We have the burden of proof. It's our case. It's our
19 witness. And that's generally the way -- the way trials --
20 trials go.

21 As of now, under the current schedule, we have 45 hours
22 of trial time remaining and that's as -- as of 1:00 today --
23 or 2:00 today.

24 With respect to deposition designations, which is
25 another issue I suspect my friends on the other side will

1 talk about, plaintiffs have designated 18.9 hours and
2 defendants have designated 7.3 of testimony for a total of
3 26.2 hours. Of that testimony designated, however, over
4 one-third of the testimony is subject to defendants'
5 objections, which we haven't received rulings from the
6 Court, so we don't know whether it's in or not, but just --
7 I wanted just to give you that background on that.

8 In these past 20-some days, or over the course of the
9 schedule, six of our 30 trial days are scheduled to be
10 half-days and we think roughly those afternoons we miss
11 roughly account for our deposition designations and they
12 should be treated that way.

13 What's left? Plaintiffs have 14 witnesses left after
14 we finish with Mr. Rannazzisi. It is possible a couple of
15 those witnesses could be dropped depending on how the other
16 testimony comes in and we continue to re-evaluate what our
17 -- what case we're putting on.

18 This morning, we decided to drop Dr. Davies from our
19 list, so we went from 15 to 14 witnesses. We've really done
20 our homework in trimming the case down to what we think is
21 the bare bones left of what we need. The witnesses are both
22 necessary for our case and non-cumulative.

23 Most of the witnesses are very short witnesses. We
24 estimate that nine of the witnesses will take an hour or
25 less on direct.

1 In total after --

2 THE COURT: You have to prove that to me, Mr.
3 Majestro.

4 MR. MAJESTRO: And I -- and I -- somebody said
5 that to me last night. The witness I put on was an hour and
6 I -- and so, it can be done. Mr. Farrell does a very good
7 job of putting short witnesses on. We can do it and we
8 think we will.

9 So, in total, and what I have is this. These are the
10 witnesses and the range of the time we believe we have left.
11 The number in the left column is the low end. The number in
12 the right column is the high end. As you can see from the
13 total, which I had Excel do the math because otherwise --

14 THE COURT: Can you put that up over here where I
15 can see it? If you can't, it's okay.

16 MR. MAJESTRO: How about -- Your Honor, if I can
17 approach, I'll let you have my copy.

18 THE COURT: Yes. That will be fine. You probably
19 will need this back, Mr. Majestro.

20 MR. MAJESTRO: And if I got it back, I would
21 probably lose it, so you're -- you're welcome to it.

22 So, those are the -- those are the witnesses that we
23 think we have left, left in this case. As you can see,
24 they're all important witnesses and we believe they are key
25 to our ability to prove our case.

1 If defendants' cross examination is in the same
2 proportion as it's been throughout the trial, that average
3 of the -- and I think I said it was the 57/42 percent of the
4 time there's a chance we could finish by next Friday, but
5 what we -- our fear is and how things have been bogging down
6 lately is that the cross examinations will be long and that
7 we are not -- we will not be in control over whether or not
8 we need to put on those important witnesses if we are stuck
9 with a set time.

10 So, the other -- the other point I would make is, and
11 we talked to Ms. Skinner about this and mentioned that we
12 also do have the two Friday afternoons remaining, which we
13 would not object to hearing testimony at that time, if the
14 Court -- if that's okay with the Court. But we understand
15 -- you know, we're just putting that -- we're just putting
16 that out there.

17 THE COURT: That's only going to give you the
18 equivalent of one more day.

19 MR. MAJESTRO: Exactly. I'm not sure that would
20 be enough and, really, whether it's enough or not is not in
21 our control other than by removing witnesses. That's the
22 only -- that's -- that's essentially the problem we have.

23 And, you know, we acknowledge that this trial has taken
24 longer than any of us anticipated. This is -- but this is
25 an important case. We could pick at the defendants for

1 their -- for individual crosses, like the five hours cross
2 on Dr. McConnell after a two-hour direct, but they would
3 likely point out Jan Rader and Dr. Courtright where they
4 didn't cross at all.

5 While it was our choice to call defendants' witnesses
6 in our side of the case, a large portion of defendants' case
7 was put in during that period of time.

8 Testimony in this case has gone slower because, for
9 what I'm experiencing, it is an unprecedented number of
10 objections in this case. And many of the objections -- and,
11 you know, just watching this morning while I was preparing
12 this argument, many of those objections either get overruled
13 or cured. That slows the case down.

14 Now, we're not saying they don't have the right to make
15 those objections, but we're pointing out that the nature of
16 the objections in this trial has lengthened it beyond what
17 we had anticipated. And, again, I'm not saying they're at
18 fault. I'm just saying this is where we are and why we're
19 there.

20 And in conclusion, Your Honor, we believe this is an
21 important case. This is a complex case. This is the very
22 first trial against an opioid distributor and we have three
23 of them on the other side.

24 The parties are working their way through facts and
25 evidence and evidentiary objections that have never --

1 they've never been dealt with by other judges.

2 I've been joking with some of my friends that when this
3 trial is over, I'm going to do a seminar for the trial
4 lawyers entitled "Evidence Rules You Never Knew Existed"
5 because I've really learned a whole lot about evidence in
6 the course of -- in the course of this trial.

7 THE COURT: You can have Mr. Ackerman help you.

8 MR. MAJESTRO: He'd show me up, so I will let him
9 go do the one in South Carolina.

10 You know, if we started over, I think we probably could
11 do this trial -- we could be further ahead knowing all --
12 everything we know now, but that's not the world we live in.

13 So, given the importance and the complexity of this
14 case to the parties, we believe it's important for us to be
15 allowed to put on these last witnesses and if it means that
16 we bleed over into the week after the break, then those
17 couple days, given the importance of the trial, are worth
18 that sacrifice.

19 We don't believe that prejudices the defendants. They
20 still get their week break to plan. The witnesses at the
21 end are likely going to be their -- witnesses they're going
22 to be rebutting at the end of their case and it's not like
23 they don't know what they're going to say. They've deposed
24 all of these witnesses.

25 With respect to the last couple of experts -- the last

1 couple that are experts, Dr. Alexander and Mr. Barrett,
2 we're not allowed to have them testify to anything different
3 than they've already given in their reports or their
4 depositions. So, they can plan based on those -- those
5 documents that they already know about and be prepared to
6 start -- to start their case a few days, however long it
7 takes, after we get to the end of our case.

8 But, again, this is an important case. We'd like the
9 time to do it right. We've spent a lot -- we've invested a
10 lot of time, a lot of money, a lot of blood, sweat and
11 tears, and so have they. We think it's necessary to have
12 this extra time.

13 THE COURT: Well, every case is an important case
14 to the litigants and it's like somebody said, there are a
15 lot of battles in history that haven't been written about,
16 but the participants in them have found them totally
17 unforgettable.

18 MR. MAJESTRO: Well, I doubt any of us will ever
19 forget this, but I would point out this is the first
20 bellwether trial. So, it's not just important to those --
21 to our clients here. The rest of the country is watching
22 this case.

23 Unless you have any questions, I'll --

24 THE COURT: Well, let me hear from somebody on the
25 other side.

1 Mr. Hester?

2 MR. HESTER: Yes, Your Honor. Thank you, Your
3 Honor. I guess I would begin by highlighting that the Court
4 in the first status conference we had last March said this
5 was going to be six weeks for each side and the Court's been
6 very clear on that all the way through.

7 And I don't think Mr. Majestro has really identified
8 any changed circumstances that alter that calculus. I think
9 the Court was clear right from the get-go that there was
10 going to be a six-week period for each side and I think the
11 vision was, if I can at least intuit the way we saw it, Your
12 Honor, the Court was allowing sufficient time for each side
13 to present its case, but it was also setting the time in a
14 way to encourage sensible choices among the witnesses and to
15 make sensible choices about the evidence.

16 In other words, it wasn't an unlimited time. The Court
17 was encouraging the parties to winnow down their witnesses
18 and to think hard about the decisions they should make.

19 And as we look at this list that the plaintiffs have
20 given to the Court and that they've given to us, it includes
21 ten experts, Your Honor, from among that list of 14. It's
22 simply not plausible that they can be put on in an hour or
23 so, as the plaintiffs have suggested. It's not going to
24 happen that way.

25 And, frankly, if they're only put on for an hour, the

1 explanation of their methodology and opinions is not going
2 to be helpful to the Court with respect. And so, we think
3 what the plaintiffs are proposing is something that could
4 really stretch this trial out.

5 And just to illustrate this -- the lack of winnowing,
6 they're including on this list three epidemiologists; not
7 one, three, plus an economist who's speaking to the same
8 subjects that Dr. Alexander and Mr. Barrett are speaking to.
9 So, there's a lot of overlap in this list.

10 And I think the right answer is not to give the
11 plaintiffs some sort of extra time, unlimited extra time if
12 they run over but, rather, to force them to winnow this list
13 down so that there's good choices being made.

14 We were surprised, frankly, to get this list and to see
15 how long it is. And to give the Court some perspective on
16 it, in the first four weeks of trial, the plaintiffs
17 presented 19 witnesses. Here we are on the last two weeks
18 and the plaintiffs are proposing 14. It's just not
19 workable.

20 But I don't think what you're hearing from the
21 plaintiffs is some articulated reason, some change of
22 circumstance, nor any particular identification of why they
23 need so many witnesses who are overlapping. It includes,
24 for instance, witnesses who are going to testify on things
25 the Court has already heard about at quite some length. We

1 can't understand the rationale for multiple epidemiologists
2 as an example again.

3 And I think the -- the point is the plaintiffs should
4 be put to the task of winnowing down their case and Mr.
5 Majestro's request is, well, if we run over, we run over,
6 but they're clearly going to run way over. It's not going
7 to be a half a day. It's going to be radically longer than
8 that.

9 And I think we can see from what's happened in this
10 trial to date it's just not plausible to think 14 witnesses
11 could be presented in this amount of time given that it's
12 taken us four weeks to get through 19, plus the witnesses
13 among that 19, there were many fact witnesses and now we're
14 into a heavy expert phase where the crosses will necessarily
15 be longer and I think the plaintiffs are going to have to do
16 more than an hour to present these experts to the Court.

17 So, our --

18 THE COURT: Do you expect the defendants to take
19 the full six weeks?

20 MR. HESTER: I do not, Your Honor. We -- we
21 haven't fully figured that out, but we're not expecting
22 we're going to need the full six weeks.

23 THE COURT: But you probably wouldn't be willing
24 to give some of your six weeks over to Mr. Majestro, would
25 you?

1 MR. HESTER: Well, our vision has been, Your
2 Honor, that the Court gave us pretty clear directions a long
3 time ago to be thoughtful about choices we are making.
4 We've tried very hard to coordinate our cases as much as we
5 could.

6 We've certainly had some cross examinations by all
7 three, but many of the crosses have been done just by one of
8 the parties. And we've taken under advisement from the
9 Court that this would be the time allotted and we would make
10 the choices within that framework.

11 So -- and we think the situation here, the plaintiffs
12 are not really saying they're prejudiced. They're just
13 saying they want to throw in more witnesses. We don't
14 understand the benefit to the Court of having three
15 epidemiologists in the last two weeks of trial, again, as an
16 example of the point.

17 I think the plaintiffs should be put to the task of
18 winnowing down their witness list rather than just an
19 indefinite extension of time. That would be our position,
20 Your Honor.

21 THE COURT: Why do you need three epidemiologists,
22 Mr. Majestro?

23 MR. MAJESTRO: Your Honor, I think there are
24 different areas and they're going to talk about different
25 things. And, I mean, I guess, you know, if we had put one

1 of them up and had them talk about all of these areas, we'd
2 get the objection that --

3 THE COURT: They're outside the reports.

4 MR. MAJESTRO: Outside the reports. And that's
5 why -- and that's why they're short times. The times are
6 not five hours for each expert. It's an hour and a half,
7 two for some of them because they have a very discrete area
8 that they're going to cover.

9 THE COURT: Okay. Are you speaking for everybody
10 here?

11 MR. HESTER: Yes, Your Honor, I am. And I would
12 just -- in addition to the epidemiologist example that I
13 gave to the Court, the other example I would give is law
14 enforcement. The Court has heard quite a bit from law
15 enforcement and individuals in the community and their
16 proposal now is for, again, more law enforcement witnesses.

17 And we feel this is not a sensible winnowing as we're
18 down toward the end of the case. There should be an effort
19 to narrow down what the plaintiffs are proposing. 16 or 14
20 witnesses in the last two weeks after we've gone through 19,
21 it's -- it's totally unworkable.

22 THE COURT: Well, here's what I propose we do.
23 Finish this week and see where we are at the end of this
24 week. We'll have one more week left and we'll take a look
25 at that at that time.

1 MR. MAJESTRO: Okay.

2 MR. HESTER: Your Honor, I would also highlight
3 this point about the deposition designations. They are a
4 substantial amount of time that's being presented to the
5 Court for its viewing pleasure.

6 THE COURT: Yeah. And if you didn't have a lazy
7 judge, I could have spent last week taking care of those.

8 MR. HESTER: I don't think we have one, Your
9 Honor. I think we have somebody who works pretty darn hard.
10 We -- and that's a real problem, too, and we've been
11 surprised to see the volume of deposition designations and,
12 as the Court will recall, the plaintiffs agreed that the
13 deposition designations would count against their trial
14 time. So that is another factor that needs to be added in.

15 And the plaintiffs have already designated quite a bit
16 of deposition testimony, but we believe they're proposing to
17 designate even more. And we think it has to end, as I think
18 all good things must come to an end, and there's some
19 benefit in having a time constraint that forces choices.

20 MR. MAJESTRO: Yeah. On the deposition
21 designations, Your Honor, we're done. We've designated them
22 all. And they're not submitted yet. Still going through
23 the process of objections and things, but the numbers I gave
24 you in terms of hours include every -- all of our
25 designations.

1 And, you know, and there is -- as I said, there is a
2 substantial amount of counter-designation including, you
3 know, one deposition we designated a witness and they aren't
4 designating his other testimony in the deposition. They're
5 designating a deposition that was taken in another --
6 another deposition that was taken in another case. So,
7 there's a lot of testimony they're putting in through the
8 designation process.

9 And, again, when you count the afternoons that we
10 haven't had trial testimony, we think it roughly -- it
11 roughly balances out, especially when -- when, I mean, I
12 think I might be more inclined to agree to count the
13 deposition time if the defendants were to withdraw all of
14 their other objections, also, but I don't see that
15 happening.

16 And, you know, the one thing I want to -- want to point
17 out on in terms of the reason these witnesses are going to
18 be -- we think they'll go faster, is the ones that we got
19 bogged down on were the adverse witnesses. And so, we can
20 put on these -- our experts and our direct testimony, we
21 believe that can come in quicker because we're in more
22 control over the -- over what the topics are going to be and
23 we know and we have -- we aren't cross examining actual
24 adverse witnesses. So, we think that that would work.

25 THE COURT: Well, let's -- let's see where we go

1 in the next couple of days and you can be mindful of the
2 clock running out on you, Mr. Majestro.

3 MR. MAJESTRO: We are acutely aware. I picture
4 the hour glass with the sand dropping down.

5 One other question, a note Mr. Ackerman passed me, and
6 I'll pass on. Is -- would going this Friday afternoon be an
7 option or should we just take -- we take that as the week
8 goes?

9 THE COURT: Well, I think -- I think it would be.
10 Do you have any objection to that, Mr. Hester?

11 MR. HESTER: Well, I don't, Your Honor, but Mr.
12 Majestro is using that time twice. He proposed to use that
13 time to count against his deposition designations, too.

14 And so, there has to be -- again, I think the
15 plaintiffs have some choices to make if they -- if their
16 proposal is to use that for in-court time, the deposition
17 designations have to count against the balance of their
18 time.

19 THE COURT: Well, and the quitting at noon on
20 Friday, there were two reasons for that. I knew that people
21 would want to get out of town and probably and go cover
22 their home front and everything. And the other thing was
23 just to help me out a little bit.

24 Ms. Wicht, you've been standing there. Do you want to
25 say something?

1 MS. WICHT: I'm sorry, Your Honor. I wanted to
2 just add one point, not disagreeing, obviously, with
3 anything Mr. Hester spoke to.

4 I did just want to add, Your Honor had inquired about
5 the time for the defense case and I just want to make sure
6 that we're clear that we do reserve the right to take the
7 full six weeks. I mean, we've seen in the plaintiffs' case
8 that, you know, they -- they've added this late designation
9 of an expert, Jakki Mohr, who is on an entirely new subject
10 that has not been discussed in the trial yet at all. So,
11 without knowing what's coming in the next, you know,
12 remaining time that they have, I just want to be clear on
13 that.

14 MR. MAJESTRO: And a final point I'd make, Your
15 Honor, is, you know, law enforcement witnesses, Mr. Dial has
16 roles other than law enforcement. That's why he's being
17 called. And I would note that we have a bunch of subpoenas
18 from the defendants for more law enforcement people, so
19 evidently they haven't heard enough about what the local law
20 enforcement have to say because they're going to call them
21 in their case.

22 THE COURT: Well, let's -- let's see. You have
23 something else to say, Mr. Hester?

24 MR. HESTER: Well, not really, Your Honor. I just
25 -- I guess I wanted to have a little clarity on what the

1 marching orders are. I mean, should the objective be that
2 we're working as hard as we can to finish by the 18th of
3 June?

4 THE COURT: I think so. I think the plaintiffs
5 should make an effort to finish within the time allotted and
6 use the time as efficiently as you can the rest of this week
7 and, on Thursday on Friday, I'll look at this again.

8 MR. MAJESTRO: Well, hopefully, we'll have this
9 witness off the stand by then. Thank you, Your Honor.

10 MR. HESTER: Thank you, Your Honor.

11 THE COURT: That was a shot across the bow, wasn't
12 it?

13 Okay, Ms. Singer and Mr. Rannazzisi.

14 I'll say one thing. I know we had an inquiry about
15 whether we had to keep wearing a mask and I'm looking
16 forward to the moment where we don't have to wear them
17 anymore. I'm working on that. I don't want to get my --
18 get cross threaded with my chief judge or get my court clerk
19 in trouble, but we're mindful of the fact that we need to do
20 something about that or at least if we can.

21 Okay. You can resume the witness stand, Mr.
22 Rannazzisi.

23 THE WITNESS: Thank you, Judge.

24 BY MS. SINGER:

25 Q. All right. Mr. Rannazzisi, let's, if we may, briefly

1 finish off our discussion about guidance from the DEA to
2 defendants and I want to start with P-08861, please.

3 MS. SINGER: Your Honor, may I approach?

4 BY MS. SINGER:

5 Q. Mr. Rannazzisi, I'll ask you to turn to P number 10 in
6 the document I just handed you. And do you recognize the
7 document that begins at P-10?

8 A. Yes, I do.

9 Q. And what do you recognize it to be?

10 A. The Diversion Investigators Manual.

11 Q. And what is the Diversion Investigators Manual?

12 A. It's a manual that -- diversion investigators are
13 trained with at Quantico, Virginia and then the manual that
14 they are supposed to make reference to during their
15 day-to-day diversion activities.

16 Q. And did you see this manual during your time at DEA?

17 A. Yes.

18 Q. And do you know the date of this manual?

19 A. This one is dated April 16th, 1996.

20 Q. Now, is this a document that's typically shared with
21 registrants?

22 A. No, it's not.

23 Q. And do you happen to know whether this Diversion
24 Investigator Manual was shared with any distributor?

25 A. It appears that this manual was shared or provisions of

1 the manual were shared.

2 **Q.** So, let's turn, please, to Page 11. So, that first
3 full page of this manual. I'd direct you to 5126,
4 requirement to report suspicious orders. Do you see where
5 that is?

6 **A.** Yes.

7 **Q.** And can you read the second sentence of that first
8 paragraph beginning DEA Field Offices?

9 **A.** DEA Field Offices will provide the supplier with the
10 related registration information whether the customer is
11 currently registered with DEA.

12 **Q.** I think we're in different places. I'm talking about
13 DEA Field Offices are not to approve or disapprove. It's
14 the second sentence of the second paragraph -- of the first
15 paragraph under 5126.

16 **A.** Oh. DEA field offices are not to approve or disapprove
17 supplier shipments of controlled substances.

18 **Q.** And the next sentence?

19 **A.** The responsibility for making the decision to ship
20 rests with the supplier. An exception to this occurs when a
21 supplier complies with DEA Field Office's request to
22 initiate controlled delivery of controlled substances.

23 **Q.** And then let's go to the bottom of the page,
24 registrants who routinely report.

25 **A.** Registrants who routinely report suspicious orders, yet

1 fill these orders, with reason to believe they are destined
2 for the illicit market, are expressing an attitude of
3 irresponsibility. It is a detriment to the public health
4 and safety as set forth in 21 U. S. C. Section 823 and 824.

5 **Q.** And just the one last section. If you look down that
6 paragraph to this activity over extended periods of time.

7 **A.** This activity over extended periods of time would lead
8 a reasonable person to believe that controlled substances
9 possibly are being diverted. An investigation will be
10 conducted for possible violation of the CSA and regulations
11 upon determining that the reporting registrant, as a general
12 practice, does not voluntarily halt shipments of controlled
13 substances to registrants involved in suspected diversion or
14 to registrants against whom previous action has been taken.

15 **Q.** Okay. You can stop there, Mr. Rannazzisi. And does
16 this reflect the instructions that DEA provided to its
17 diversion investigators?

18 **A.** Yes, it does.

19 **Q.** And is that the direction they were given for their
20 communications with registrants?

21 **A.** Yes.

22 **Q.** Okay. Let's turn now please to the second Rannazzisi
23 letter, P-00032. It's back? Okay. I think you have that
24 in front of you. It's part of a packet you received
25 previously.

1 **A.** Yes, I've got it.

2 **Q.** Okay. And do you recognize this document?

3 **A.** Yes.

4 **Q.** And what do you recognize it to be?

5 **A.** A letter to Cardinal Health. In this case, it was to
6 the Syracuse, New York facility.

7 **Q.** Okay. And was this a letter you approved?

8 **A.** Yes.

9 **Q.** And is it a letter that you signed?

10 **A.** Yes.

11 MS. WICHT: Ms. Singer, I'm sorry to interrupt
12 you. I'm trying to make sure the witness testified this was
13 to Cardinal Health at Syracuse and I'm not seeing that on
14 the document. I'm just trying to determine if I am on the
15 same document that the witness and that you are on.

16 MS. SINGER: So, the witness is looking at
17 hopefully --

18 BY MS. SINGER:

19 **Q.** What is the date of the letter you are looking at, Mr.
20 Rannazzisi?

21 **A.** December 27, 2007.

22 **Q.** Okay. So, can you move, Mr. Rannazzisi, to the one
23 that's February 7th, 2007?

24 MS. WICHT: Could we have the P number perhaps,
25 Ms. Singer? I think maybe I --

1 MS. SINGER: It is P-00032. And we're actually
2 not going to discuss the document itself.

3 MS. WICHT: I'm just -- it's not to Cardinal
4 Health.

5 BY MS. SINGER:

6 **Q.** So, Mr. Rannazzisi, if you don't mind just following on
7 the screen --

8 THE COURT: Do you have the right one?

9 MS. WICHT: Well, I do have the one that Ms.
10 Singer referred to. I'm concerned that I don't have the
11 same one that the witness is referring to because the
12 version that Ms. Singer and I are talking about is not
13 directed to Cardinal Health.

14 MS. SINGER: So, rather than, with the Court's
15 permission, spend time on this, I'm just going to ask the
16 witness to identify the document and then move on.

17 THE COURT: Okay.

18 BY MS. SINGER:

19 **Q.** So, Mr. Rannazzisi, looking at the screen, do you
20 recognize this document?

21 **A.** Yes.

22 **Q.** And what do you recognize it to be?

23 **A.** A letter to the registrants on February 7th, 2007.

24 **Q.** And was this a letter you approved and signed?

25 **A.** Yes.

1 Q. And why did you send this letter?

2 A. That is almost the exact same letter as the September
3 letter and -- it is the same letter as the September letter.
4 We felt that there were some registrants who did not get the
5 September letter, so we re-sent it.

6 Q. Okay. And why was that -- why did you want to make
7 sure everyone had seen it?

8 A. Because, again, we wanted to make sure that everybody
9 understood their obligations under the Controlled Substances
10 Act.

11 Q. All right. Let's turn in the same package and we're
12 also going to move through this letter quickly to P-00032,
13 Page 3, and it should be the December 7th -- December 27th
14 letter.

15 A. Okay.

16 Q. All right. Do you have that letter?

17 A. Yes.

18 Q. And do you recognize this letter, Mr. Rannazzisi?

19 A. Yes.

20 Q. And is this -- did you approve this letter?

21 A. Yes.

22 Q. And did you sign and did DEA send this letter?

23 A. Yes.

24 Q. And to whom was this letter sent?

25 A. Again, all distributors and manufacturers in the United

1 States.

2 **Q.** Okay. And I just want you to take a moment rather than
3 reading out loud. Could you just look at Paragraphs 3 and 4
4 and explain to the Court what guidance or direction you were
5 providing in that part of the letter?

6 **A.** Just saying that a suspicious --

7 THE COURT: I'm sorry.

8 THE WITNESS: Paragraph 3 brings attention to the
9 requirement to report suspicious orders when discovered and
10 filing the Excessive Purchase Report, or whatever you want
11 to call it, it doesn't meet the regulatory requirement to a
12 suspicious order.

13 **Q.** And then, turning the page to the second page, second
14 full paragraph, what direction is DEA providing in that
15 paragraph beginning when reporting?

16 **A.** All this is saying is if you rely on a rigid formula
17 you may be missing suspicious orders and, therefore, not
18 complying with the act. We use the example that if you
19 started your system when a pharmacy was ordering very large
20 quantities it's not going to pick up a suspicious order
21 because that -- that pharmacy began by ordering large
22 quantities.

23 **Q.** Now, does this letter from you to registrants impose
24 any new requirements or different guidance?

25 MR. SCHMIDT: Objection, foundation for the same

1 reasons said this morning. He's testified that he doesn't
2 -- he wasn't involved before 2005.

3 MS. WICHT: And I'm sorry.

4 MS. SINGER: This is a 2007 letter.

5 MS. WICHT: I would further object that it's a
6 legal conclusion to the extent that Ms. Singer is asking
7 about requirements as opposed to just guidance.

8 THE COURT: Well, I'll sustain the objection to
9 the specific question. Maybe you can get at it another way,
10 Ms. Singer.

11 BY MS. SINGER:

12 **Q.** To your knowledge, Mr. Rannazzisi, were you saying
13 anything different in this letter than DEA said before?

14 **A.** No.

15 **Q.** Did you receive, to your knowledge, any response from
16 defendants after you sent these letters?

17 **A.** No.

18 **Q.** Do you expect you would have been told if there were
19 complaints or questions about these letters?

20 MR. SCHMIDT: Objection, speculation and
21 relevance.

22 THE COURT: Well, I'll overrule the objection.
23 You can answer it, if you can, Mr. Rannazzisi.

24 THE WITNESS: If there was some problem with the
25 letters, I would have been notified because they were my

1 letters by my staff.

2 BY MS. SINGER:

3 **Q.** Now, do you consider each of those three letters to be
4 official guidance of DEA?

5 **A.** Yes.

6 MR. WICHT: Object to the extent that I'm not sure
7 what the term "official guidance" is, if it's -- I mean,
8 there is law about that, so I will object to the extent that
9 it's being asked as a legal conclusion.

10 THE COURT: Overruled. The question is do you
11 consider each of these three letters to be official guidance
12 of the DEA. You can answer that, Mr. Rannazzisi, if you
13 can.

14 THE WITNESS: Yes, I do consider it.

15 BY MS. SINGER:

16 **Q.** And is there a reason you sent this guidance through
17 letters rather than, for instance, a formal rule making?

18 **A.** Because these letters were -- there was no change in
19 the regulation or the law. We sent these letters just to,
20 again, reiterate what the responsibilities were.

21 **Q.** All right. You can put those documents aside.

22 Do you remember, Mr. Rannazzisi, whether in the last
23 letter you referred to a particular administrative order or
24 a particular case?

25 **A.** Yes, ma'am.

1 Q. And what was that case?

2 A. Southwood Pharmaceutical.

3 MS. SINGER: I'm going to circulate P-23726,
4 please.

5 May I approach, Your Honor?

6 BY MS. SINGER:

7 Q. Mr. Rannazzisi, do you recognize P-23736?

8 A. Yes, I do.

9 Q. And what is it?

10 A. This is a final decision and a revocation of
11 registration of Southwood Pharmaceuticals.

12 Q. And what was Southwood?

13 A. Southwood was -- I guess you would consider them a
14 manufacturer, but they were a re-packager. So, they
15 re-packaged drugs and distributed them. They had
16 distribution authority just like the distributors would.

17 Q. And did you play a role in the Southwood revocation?

18 A. Yes.

19 Q. And what was that role?

20 A. I approved -- I chopped off, read and gave my approval
21 on the Order to Show Cause and we attached an Immediate
22 Suspension Order that would be sent to the Deputy
23 Administrator for final review and approval.

24 Q. And I know you've used this term before, "chopped".
25 What does that mean?

1 **A.** When these come through my office, if it's an Immediate
2 Suspension Order, there's a list of people who look at it
3 before it gets to me and, once I read it, read the whole
4 document, make sure that it's correct and violations are in
5 place, at that point in time, I'll initial it and it goes up
6 to the Administrator, the Deputy Administrator.

7 **Q.** And that process is what you refer to as a "chop"?

8 **A.** It's a chop, yeah.

9 **Q.** And was there a hearing in the Southwood revocation
10 proceeding?

11 **A.** Yes, there was.

12 **Q.** And was there a decision after that hearing on the show
13 cause?

14 **A.** Yes, there was.

15 **Q.** And was there a published decision?

16 **A.** Yes.

17 **Q.** Do you remember when and where that decision was
18 published?

19 **A.** Well, the decision was published in July of 2007.

20 **Q.** And where was it published, do you know?

21 **A.** In Federal Register.

22 **Q.** And do you know if that decision was available to these
23 defendants?

24 **A.** The Federal Register is our vehicle for putting out
25 decisions. So, yes, it was available to anybody.

1 Q. Now, does the DEA provide guidance to registrants
2 through these kinds of administrative orders?

3 A. Yes.

4 Q. And does the DEA advise registrants to pay attention to
5 enforcement actions and decisions?

6 A. Yes. That's why we also put it on our website.

7 Q. And do you recognize this document as the final order
8 revoking Southwood's registration?

9 A. This is the website version of the final order. The
10 Federal Register version is in Federal Register format, but
11 this is the website, the DEA website version of it, yes.

12 MS. SINGER: Your Honor, I would move to admit
13 P-23736.

14 THE COURT: Is there any objection?

15 MR. SCHMIDT: No objection, Your Honor.

16 THE COURT: It is admitted.

17 Ms. Wicht, do you want to say something?

18 MS. WICHT: No, no. I'm sorry, Your Honor.

19 MR. SCHMIDT: Your Honor, can I amend what I said?
20 I think the Court can take notice of it. I don't think --
21 because it's a legal decision, I don't think it's properly
22 in evidence. We haven't been doing that with the other
23 decisions, but we don't object to the Court taking notice of
24 it.

25 THE COURT: Well, I will admit it. I think you're

1 right, but I will admit it anyway.

2 BY MS. SINGER:

3 **Q.** Now, did Southwood reflect or express an expectation
4 that distributors needed to know about their customers'
5 business practices in order to prevent diversion?

6 **A.** Yes. That was the whole basis of the Southwood
7 decision. They had to know their decision and they had to
8 do due diligence on their customer.

9 **Q.** And did the decision identify red flags of diversion?

10 **A.** Yes, it did.

11 **Q.** Now, I want to turn your attention to Page 13, please,
12 middle of the page, Footnote 23. And it's very small but,
13 hopefully, Gina can help us out. And I will go ahead and
14 try to read this.

15 Respondent attempts to excuse its conduct on the
16 grounds that it repeatedly asked DEA officials whether it
17 should stop selling to the pharmacies only to be told by DEA
18 officials that they could not tell them whether or not to
19 sell because that was a business decision. Respondents'
20 Brief 33.

21 Several courts have held, however, that DEA has no
22 authority under the CSA to tell a distributor whether to
23 sell or not. And then another citation.

24 Have I read that correctly?

25 **A.** Yes.

1 Q. And is that your understanding of the DEA's practices?

2 A. Yes.

3 Q. And did Southwood provide guidance on whether a
4 distributor may ship a suspicious order?

5 A. Yes.

6 Q. And what did it say on that point?

7 A. They have to evaluate the orders and if they find that
8 -- it's their decision whether to ship, but if they continue
9 to ship orders without resolving suspicions, then they're
10 not maintaining effective controls against diversion.

11 Q. And, to your knowledge, was the guidance provided in
12 the Southwood order consistent with the guidance that DEA
13 had provided in the past?

14 A. Yes.

15 Q. All right. Let's turn to -- I'm sorry. Before we do,
16 you mentioned previously, I think yesterday, Mr. Rannazzisi,
17 that DEA provided guidance through presentations at various
18 conferences and events; is that right?

19 A. Yes.

20 Q. Now, are you familiar with a pharmaceutical industry
21 conference?

22 A. Yes, I am.

23 Q. Okay. And what is that?

24 A. It brings in -- Pharmaceutical Industry Conference
25 brings in manufacturers and distributors, there's regulators

1 there, to just discuss things of importance in the field of
2 controlled substances.

3 MS. SINGER: Can we circulate P-02291, please?

4 May I approach, Your Honor?

5 BY MS. SINGER:

6 **Q.** Mr. Rannazzisi, are you familiar with the document I
7 just passed up to you?

8 **A.** Yes.

9 **Q.** And what do you recognize it to be?

10 **A.** This was part of a presentation done at one of the
11 conferences, at one of the -- the conferences.

12 **Q.** And was this -- have you seen this presentation before?

13 **A.** Yes.

14 **Q.** While you were at DEA had you seen it?

15 **A.** Yes.

16 **Q.** And is this guidance that DEA provided to distributors
17 and other registrants?

18 **A.** Yes.

19 **Q.** Do you know whether this was posted on the DEA's
20 website or whether it was the practice of the DEA to post
21 materials like this on its website?

22 **A.** Anytime DEA has a conference for transparency reasons
23 we post the conference -- the conference materials and the
24 presentations we're allowed to post, yes.

25 **Q.** And do you know whether this material was prepared and

1 provided as a part of DEA's official activities?

2 **A.** Yes, it was.

3 MS. SINGER: Move to admit P-02291, Your Honor.

4 THE COURT: Any objection to 2291? Hearing none,
5 it's admitted.

6 MS. SINGER: All right.

7 MR. NICHOLAS: No. I was just going to say no
8 objection.

9 THE COURT: It's admitted.

10 MS. SINGER: Let's move, please, to P-09616.

11 May I approach again, Your Honor?

12 BY MS. SINGER:

13 **Q.** Mr. Rannazzisi, do you recognize this document?

14 **A.** Yes.

15 **Q.** Have you seen it before during your tenure at DEA?

16 **A.** Yes.

17 **Q.** And what do you recognize this document to be?

18 **A.** In our -- in our meetings and presentations,
19 conferences, the Office of Chief Counsel also gives
20 presentations on -- on certain aspects of the Controlled
21 Substances Act.

22 **Q.** And turning to Page 2 of this document, do you
23 recognize who gave this presentation? Do you happen to know
24 who gave this presentation?

25 **A.** Well, this presentation has been given by a number of

1 people. I could list names, if you like.

2 **Q.** Do you know if this presentation was presented at DEA
3 conferences?

4 **A.** Yes.

5 **Q.** And do you know whether this presentation would have
6 been posted on DEA's website?

7 **A.** Yes.

8 MS. SINGER: I would move to admit P-09616.

9 THE COURT: Any objection?

10 MR. SCHMIDT: Our only objection is foundation. I
11 don't think there's a foundation laid with this witness. He
12 is not an expert.

13 THE COURT: Overruled. I'm going to admit it.

14 BY MS. SINGER:

15 **Q.** Mr. Rannazzisi, can you turn to Slide 9, please? Do
16 you know what these bullet points on this slide represent?

17 **A.** I'm sorry?

18 **Q.** Do you know what the bullet points on this slide
19 reflect?

20 **A.** Oh, they reflect excuses that the DEA has heard about
21 why they are not living up to their obligations under the
22 act.

23 MS. WICHT: Objection, foundation and hearsay,
24 Your Honor.

25 THE COURT: Overruled.

1 BY MS. SINGER:

2 Q. And was it your -- do you believe that any of these
3 were valid reasons for DEA -- for DEA registrants not to
4 identify suspicious orders or practices?

5 A. No.

6 Q. Let's turn to Slide 13, please. And does this slide
7 also reflect guidance that DEA provided to registrants?

8 A. Yes. This is -- this slide is consistent with
9 guidance.

10 Q. All right. All right. We can put that one away.

11 All right. Mr. Rannazzisi, I think the next stop on
12 our road tour that we talked about yesterday was ARCOS and I
13 want to turn there now. Did you have a chance to work with
14 ARCOS data as a law enforcement officer at the DEA?

15 A. I worked with ARCOS data as a diversion investigator in
16 the late 80s and then in my role as Deputy Director and then
17 Deputy Assistant Administrator.

18 Q. And does the DEA receive ARCOS data from distributors,
19 from these defendants?

20 A. Yes.

21 Q. And do you know when they receive ARCOS data? How
22 often is it reported?

23 A. It depends. Some -- some people report it monthly.
24 Some quarterly. Just depends on the registrant and their --
25 how they want to report.

1 Q. Okay. And how is that -- how is that requirement set?
2 Is that a matter of discretion?

3 A. If we allow the registrants to make that determination,
4 yes.

5 Q. Okay. And is it governed by any statutory framework?

6 A. I believe it's in P-27.

7 Q. And do you know whether the settlement agreements with
8 any defendants require them during the time of those
9 agreements to report ARCOS data more frequently?

10 A. Yes. I believe in the settle agreements we did have a
11 modified ARCOS Report in the settlement agreements, yes.

12 Q. Now, what happens after DEA receives that information?
13 Is there anything that DEA needs to do with it?

14 A. Well, the problem with ARCOS is it's kind of raw data
15 and it's got to be validated and to validate it, we have to
16 go through it, look at the transactions, and make sure that
17 the transactions are within -- do not container errors.

18 Q. And have there been issues in the past where DEA --
19 DEA's validation process founders errors in the ARCOS data?

20 A. Yes, we have founder errors in the ARCOS data.

21 Q. And can you provide an example of the type of error
22 that you might find?

23 A. Just quantity errors, strength errors, things like that
24 that could throw the system off.

25 Q. Now, how long does it take DEA to validate ARCOS data

1 after it receives it?

2 **A.** I can't tell you how long it takes now, but when I was
3 there, anywhere from three to five months for validation.

4 **Q.** And is that something that DEA has to do in order to
5 use that ARCOS data to conduct investigations or enforcement
6 actions?

7 **A.** Yes.

8 **Q.** And why is that?

9 **A.** We can't use the raw data because we don't want to open
10 an investigation based on data that's flawed.

11 MS. SINGER: So, I want to try, with the Court's
12 permission, to use our white board, if my technological
13 skills are up to it.

14 BY MS. SINGER:

15 **Q.** All right. Mr. Rannazzisi, is there certain data --
16 and let me get my mic.

17 Is there certain data that distributors have that is
18 different than the data DEA has?

19 **A.** Well, yeah. There's a lot of data that distributors
20 have that the DEA doesn't have.

21 **Q.** So, for instance, does -- do defendants report through
22 ARCOS every controlled substance they ship?

23 **A.** No, ma'am.

24 **Q.** And what controlled substances are reported by
25 distributors through ARCOS?

1 **A.** Schedule I and II and III narcotics. The distributors
2 wouldn't have Schedule I. So, Schedule -- say Schedule II
3 and III narcotics. All Schedule IIs and III narcotics.

4 **Q.** Now, do contributors have data on all of their
5 controlled substances that they sell?

6 **A.** Yes. That's a requirement.

7 **Q.** Okay. So, if I put all drugs here, is that accurate?

8 **A.** All -- all controlled substances, yes.

9 **Q.** All controlled substances and DEA has Schedule I,
10 Schedule II?

11 **A.** Schedule II and Schedule III narcotics.

12 **Q.** Schedule II and III. Thank you. And in terms of
13 timing, when do defendants have access to controlled
14 substance shipments or orders? Is that available right away
15 or is there a time lag?

16 **A.** What, the distributors, whether they -- they have it
17 available immediately. They've taken the orders.

18 **Q.** And I think you testified a minute ago that DEA only
19 gets that data sometime after; is that correct?

20 **A.** Yeah. Well, it depends on the month or every quarter,
21 yeah.

22 MR. NICHOLAS: Your Honor, could I interpose a
23 modest request or an objection for a time period?

24 THE COURT: Yes. I think that would be
25 appropriate.

1 Do you have a time period?

2 BY MS. SINGER:

3 **Q.** So, can we speak, Mr. Rannazzisi, to your tenure as
4 Deputy Assistant Administrator? Is what you've testified to
5 true to that time period?

6 **A.** Yes.

7 MS. SINGER: I thought you might have objected to
8 my handwriting, which would have been fair.

9 BY MS. SINGER:

10 **Q.** Now, did -- do distributors have data, to your
11 knowledge, on drugs other than controlled substances that
12 they sell?

13 **A.** I'm sure they do, but it's not in -- they don't have to
14 report anything that's not a controlled substance, so I
15 concentrate strictly on controlled substances.

16 **Q.** So does DEA get access through any vehicle to
17 non-controlled substance data through ARCOS or other
18 reporting by distributors?

19 **A.** No.

20 **Q.** Now, is it important in detecting diversion to know how
21 many controlled substances a customer is buying versus
22 non-controlled substances?

23 **A.** Yes.

24 **Q.** And why is that important?

25 **A.** Because if a customer is ordering an inordinate amount

1 of controls as compared to non-controls, that's a red flag.
2 That's an anomaly. That doesn't happen.

3 **Q.** And do you know whether defendants have data on whether
4 a pharmacy's drugs are being paid for by -- with cash?

5 MS. WICHT: Your Honor, may we lay some foundation
6 as to how this witness has any knowledge of what data
7 distributors, any particular distributor has or does not
8 have?

9 THE COURT: Well, I'll sustain the objection and
10 you can lay the foundation, Ms. Singer.

11 MS. SINGER: All right.

12 BY MS. SINGER:

13 **Q.** Mr. Rannazzisi, in your capacity in supervising
14 investigations and as the Chief Enforcement Officer, did you
15 come to learn what data distributors have and use in their
16 compliance programs?

17 **A.** Yes.

18 **Q.** And how did you come to know that?

19 **A.** Because I used to review those cases.

20 **Q.** All right. So, let me ask you again. Do you know
21 whether defendants had access to information on whether
22 drugs were -- what drugs purchased from their customers were
23 paid for in cash?

24 MR. WICHT: Your Honor, I apologize. I don't --
25 Mr. Rannazzisi has referred to learning this through various

1 cases. Ms. Singer is asking very generally about all
2 distributors. I don't think there's any foundation for him
3 to say anything like that as to all distributors or as to
4 the particular distributors who are in this room as of right
5 now.

6 MR. SCHMIDT: We join, especially because this is
7 being presented as kind of a categorical, we've always had
8 this, they never did, and he doesn't have the foundation for
9 that.

10 MR. NICHOLAS: We'd join, as well.

11 THE COURT: Well, ask him how he knows, if he
12 knows.

13 BY MS. SINGER:

14 **Q.** So, Mr. Rannazzisi, do you know, first of all, whether
15 these defendants had data on -- on whether drugs -- whether
16 drugs were being purchased with cash from their customers?

17 **A.** I don't know if they had that data.

18 **Q.** And did DEA have that data?

19 **A.** No. DEA definitely didn't have the data.

20 **Q.** And do you know in your capacity as Deputy Assistant
21 Administrator whether there was other data that distributors
22 had access to that was useful in identifying potential
23 diversion?

24 MS. WICHT: I'm sorry. I'm just again going to
25 ask for it not to be posed as distributors generally.

1 That's not relevant and he needs to have foundation to talk
2 about these distributors.

3 THE COURT: Well, I'm going to overrule the
4 objection and let her go ahead.

5 THE WITNESS: Yes. There's other data that could
6 be purchased that could help them find that information.

7 BY MS. SINGER:

8 Q. And what kind of information are you talking about?

9 A. IMS Health data, Switch data, Chargeback data, any
10 number of things that they had access to.

11 Q. And what does that Chargeback, IMS and Switch data
12 show?

13 A. Well, it depends on the aggregator. It depends on the
14 company. But it could show anything from third party --
15 third party payers in the prescription arena to cash sales.
16 It could show you how much a pharmacy is dispensing out and
17 you could make your comparison based on what you're
18 dispensing -- what you're distributing to the pharmacy and
19 how much you're dispensing out to figure out if there was
20 another distributor out there distributing to that pharmacy.
21 So, there's a lot of different things you could find with
22 this data.

23 Q. And do you know whether distributors had access to
24 prescribing data, as well?

25 MR. SCHMIDT: We'll make the same objection. I

1 think the problem with this is -- and he's actually giving
2 opinions in other cases as an expert that we should have
3 acquired some of this data that we did not, in fact, have.
4 The problem with this suggestion is all distributors
5 necessarily includes us and necessarily includes all data in
6 this area. So, I guess the objection is vague. No
7 foundation.

8 THE COURT: Well, I'm going to over -- I'm sorry,
9 Ms. Wicht. Go ahead.

10 MS. WICHT: I'm sorry, Your Honor. I just -- I
11 would join the foundation objection and say that it's
12 assuming facts that are not in evidence in this case and
13 that I think that the demonstrative that's being created is
14 -- is misleading, respectfully, in that it lists things
15 under distributors that he's not testified he has any
16 knowledge that distributors had.

17 THE COURT: Well, I'm going to overrule the
18 objection. I think cross examination can probably take care
19 of any problems here and let's get on with it and get this
20 done.

21 BY MS. SINGER:

22 Q. So, Mr. Rannazzisi, I think I asked you about
23 prescribing data and I'm not sure whether you answered.

24 A. I guess -- what type of prescribing data are you
25 looking for?

1 **Q.** Who was prescribing controlled substances and what
2 dosages, et cetera?

3 **A.** I'm sure that -- well, that could be obtained through a
4 third party aggregator, as well, or they could just ask
5 their customers.

6 **Q.** And did DEA have this information that you just
7 described, payers dispensing or prescribing?

8 **A.** I can't -- this is one of those areas where the
9 Department has directed me not to discuss what law
10 enforcement tools we used.

11 MR. SCHMIDT: In that case, Your Honor, we'll move
12 to strike this testimony because the point is to show that
13 we were doing something DEA didn't have and we can't even
14 challenge that.

15 THE COURT: Mr. Farrell?

16 MR. FARRELL: Again, I would just simply point out
17 that this is a -- an issue with a long tail to it. The
18 Department of Justice is here and if the Department of
19 Justice doesn't object, I would assume this witness is being
20 careful and can proceed.

21 THE COURT: Mr. Westfall?

22 MR. WESTFALL: Yes, Your Honor. This situation
23 was covered in his deposition. There are certain types of
24 databases that are law enforcement tools and techniques that
25 are used and we have instructed him not to disclose those

1 and we're kind of -- it's one thing to talk about databases
2 that are public, but now we're getting into the areas that
3 are starting to approach some of our law enforcement tools.
4 And so, I would instruct him not to disclose any of that
5 information that is basically non-public.

6 MR. NICHOLAS: Well, in that case, Your Honor, I
7 do think this line of questioning and the demonstrative is
8 highly prejudicial and misleading.

9 MS. SINGER: So, Your Honor, if I may, I think
10 putting aside whether an objection to the tools and data
11 that was available to DEA in 2015 when Mr. Rannazzisi was
12 there, so we're talking about data now six years old, would
13 reveal confidential informant law enforcement strategies,
14 the fact is that Mr. Rannazzisi has testified about all of
15 the data that distributors had or had access to to detect
16 diversion.

17 Frankly, whether DEA had none of it or all of it only
18 goes to show an imbalance but doesn't -- doesn't make any
19 less relevant the data distributors had to implement their
20 own programs.

21 MR. SCHMIDT: I think the witness to that point
22 has gone back and forth between saying maybe we had it,
23 maybe we didn't, maybe we should have bought it. That would
24 be an expert opinion absent some historical tether. He
25 doesn't know. He doesn't have the foundation as to us.

1 THE COURT: Well, I'm going to go ahead and let
2 him testify and then I will decide to what extent, if at
3 all, I'll consider it.

4 Is it your position that the defendants had an
5 obligation to go out and find other data and determine
6 whether that revealed diversion or not? Is that the point?

7 MS. SINGER: So, I think the testimony, for
8 instance, in Mr. Prevoznik's deposition for the DEA, which
9 we've designated, is that the defendants had an obligation
10 to use any data available to prevent diversion, the data
11 they had, and I don't think Mr. Rannazzisi has offered
12 testimony as to should. I think he's only testified as to
13 what they could have done or had access to or had.

14 THE COURT: Well, I'm going to go ahead and take
15 the testimony and then I'll decide to what extent, if any,
16 I'm going to consider it.

17 BY MS. SINGER:

18 **Q.** Now, putting aside the demonstrative, did DEA still
19 make use of ARCOS data with what it had and when you got it
20 during your tenure?

21 **A.** Yes, we did make use of ARCOS data.

22 **Q.** And without going into sensitive law enforcement
23 details, how did DEA use ARCOS data?

24 **A.** We looked at drugs going downstream in volume to see
25 what pharmacies were getting larger volumes of drugs.

1 **Q.** And did you personally use ARCOS data as an
2 investigative tool?

3 **A.** I have been involved with, you know, others in my
4 office going through ARCOS data, yes.

5 **Q.** And is that something you did frequently?

6 **A.** It was done during a period of time, yes. It was
7 frequent during a period of time.

8 **Q.** And did -- did the data distributors have, in your
9 experience, to your knowledge, provide defendants with the
10 ability to identify diversion?

11 **A.** Yes, based on the -- on the ARCOS data, there's certain
12 things they should have picked up. Regardless of what we
13 didn't have, they should have picked up the large
14 quantities, such as the quantities that were going into
15 those internet pharmacies and then later on, the pharmacies,
16 going into the pharmacies that were involved in the pill
17 mills.

18 **Q.** Now, did distributors ask for access to ARCOS data that
19 showed them what -- I'm sorry. Did defendants ask for
20 access to ARCOS data that would show them what other
21 distributors shipped?

22 **A.** Yes. I believe defendants did at one time ask for that
23 data.

24 **Q.** And did DEA provide that data to them?

25 **A.** No, we did not.

1 Q. Why not?

2 A. We cannot -- that's another I have been instructed by
3 the Department of Justice not to answer this question.

4 Q. And are you aware that defendants raised concerns about
5 sharing confidential proprietary data with their
6 competitors?

7 A. Yes. I was aware that there was -- there were concerns
8 generally. There were concerns within the registrant
9 community, yes, I was aware.

10 Q. Now, in your -- in your experience using only data on
11 their own orders and shipments, could defendants identify
12 suspicious orders and diversion?

13 A. Yes, they could.

14 Q. Would access to other distributors' ARCOS data have
15 helped them prevent diversion? Did they need it?

16 MR. SCHMIDT: Objection. We're now in a pure
17 opinion. An opinion where -- I apologize. We're now in an
18 opinion where he said if we asked him what he was told in
19 order to challenge the opinion, we're not going to be able
20 to get an answer.

21 THE COURT: I'm going to sustain the objection to
22 that.

23 BY MS. SINGER:

24 Q. Would -- did DEA take steps to address the volume of
25 shipments that DEA was seeing through ARCOS?

1 **A.** Yes. We retrospectively looked at those volumes and
2 then again investigated them.

3 **Q.** And what do you mean retrospectively?

4 **A.** Well, remember ARCOS is only -- is generally behind
5 three to five months, maybe longer. So, those shipments
6 were already completed. So, we went back and started to
7 backtrack, looking at what was happening with that
8 particular pharmacy, and then we went back up the chain.

9 **Q.** And did you use ARCOS data and your knowledge of the
10 volume of pills defendants were selling to take enforcement
11 actions to address the volumes you were seeing at DEA?

12 MR. WESTFALL: Your Honor -- excuse me, Your
13 Honor. He can testify as to public information regarding
14 what they did with the data, but as we start getting into
15 law enforcement sensitive techniques, anything outside of
16 the information that would be publicly available --

17 THE WITNESS: That's all --

18 THE COURT: Just a minute.

19 THE WITNESS: Yes, sir. I'm sorry.

20 THE COURT: I think he can answer that question
21 without running afoul of what he's been told he can say and
22 not say.

23 So, you can answer the question, Mr. Rannazzisi.

24 MR. WESTFALL: Thank you, Your Honor.

25 THE WITNESS: That is all detailed in the Order to

1 Show Cause where information came from. So --

2 BY MS. SINGER:

3 Q. And was it -- do you believe it was possible for DEA,
4 was DEA able during your tenure, to respond to all of the
5 diversion that it was seeing at the retail level?

6 A. It was very difficult based on the resources we had at
7 that time, yes. It was very difficult.

8 Q. And can you explain that?

9 A. Well, these investigations take a lot of time. There's
10 -- at the time, there was probably about 65,000 pharmacies,
11 retail pharmacies in the United States and, you know,
12 1.3-1.4 million prescribers. So, you know, we were -- we
13 were definitely out-manned. And so, we needed help. That's
14 why the Controlled Substances Act had those obligations at
15 all levels. So, yeah, it was very difficult with all of
16 that, all those pharmacies and prescribers.

17 MS. WICHT: I believe Your Honor has previously
18 sustained objections to testimony about why the Controlled
19 Substances Act says what it says given that Mr. Rannazzisi
20 wasn't involved in its passage in 1970.

21 THE COURT: Well, I'll sustain that objection, but
22 it only goes to part of his answer.

23 So, go ahead, Ms. Singer.

24 BY MS. SINGER:

25 Q. Let's turn please to Demonstrative 226, please, Slide

1 3. All right. So, turning to Demonstrative 226, Slide 3,
2 Mr. Rannazzisi, are you familiar with 21 C. F. R. 130174?

3 **A.** Yes.

4 **Q.** And what is that?

5 **A.** That's a security provision with the act.

6 **Q.** I'm sorry. Can you say that again?

7 **A.** Security provisions with the act.

8 **Q.** And (b)?

9 **A.** 74(b)?

10 **Q.** Yes.

11 **A.** That is the suspicious order reporting provision.

12 **Q.** All right. Thank you. All right. And do you
13 recognize this as 1301.74(b)?

14 **A.** Yes.

15 **Q.** And is that the regulation that, as you've said,
16 defines what constitutes a suspicious order?

17 **A.** Yes.

18 **Q.** And did you feel a need beyond this regulation and the
19 guidance we've discussed to provide a further definition of
20 a suspicious order to defendants?

21 **A.** During my tenure?

22 **Q.** That's right.

23 **A.** No. I thought it was pretty straightforward.

24 **Q.** And did you ever pursue a rule making to more fully
25 describe what a constitutes a suspicious order?

1 **A.** No. It was pretty straightforward.

2 **Q.** And did you provide any guidance to registrants
3 regarding what records they should maintain regarding their
4 investigation of customers or orders?

5 **A.** I don't recall if I provided guidance. I don't know.
6 I don't believe it was in those letters. It might have been
7 in those letters, but I don't recall.

8 **Q.** Do you recall whether it was DEA's position or do you
9 -- let me put that more simply. Do you believe that
10 maintaining records is part of a distributor's obligation in
11 knowing their customers?

12 MR. SCHMIDT: Objection. This is a pure opinion
13 and it is an opinion where he has just said he doesn't
14 recall ever giving this guidance.

15 MR. NICHOLAS: In addition, it sounds like a
16 question that would yield a legal conclusion.

17 MS. WICHT: I join that, Your Honor.

18 THE COURT: Sustained.

19 BY MS. SINGER:

20 **Q.** Mr. Rannazzisi, are you aware of whether in conducting
21 inspections DEA -- or investigations DEA would look to what
22 records a distributor maintained on its customers?

23 **A.** Yes. They would ask for due diligence files, yes.

24 **Q.** And would it also look for records of Suspicious Order
25 Reports and investigations?

1 **A.** Yes. That would be in the due diligence files.

2 **Q.** And why was DEA looking for that information?

3 **A.** Because we wanted to see -- basically the customers,
4 what they were -- how they were evaluating their customers
5 to see how their system was working.

6 **Q.** Did you -- full stop. Did DEA ever tell distributors
7 about customers that were under investigation by DEA during
8 your tenure?

9 MR. WESTFALL: Objection, Your Honor. I think
10 we're getting -- those kinds of conversations are getting
11 deep into law enforcement sensitive techniques and perhaps
12 things of that nature because of, again, whatever might have
13 transpired between customers or -- DEA customers in those
14 areas --

15 THE COURT: I think all she's asking is if they
16 ever told distributors certain customers were under
17 investigation. I don't think that goes to the techniques
18 they were using or any sensitive law enforcement information
19 if the question was did he -- did the DEA tell them there
20 were investigations. I'll let him answer.

21 Go ahead.

22 THE WITNESS: No. We wouldn't tell them of -- of
23 companies under investigation

24 BY MS. SINGER:

25 **Q.** And why was that?

1 **A.** Because there were due process concerns. If we told
2 them that this company is under investigation and they
3 stopped shipping to them because of what we told them, we
4 would have due process issues.

5 **Q.** And were there also concerns about compromising current
6 investigations, or confidential informants, or issues like
7 that?

8 MR. SCHMIDT: Objection, leading. We now have
9 testimony --

10 THE COURT: Sustained.

11 BY MS. SINGER:

12 **Q.** I'll try to un-ring that bell. Were there other
13 reasons, Mr. Rannazzisi, that you wouldn't share this
14 information with distributors?

15 **A.** Well, the other reason is the Department of Justice
16 policy is that we can't disclose ongoing investigations.

17 **Q.** Was that always, during your tenure, DEA's policy?

18 **A.** Yes.

19 **Q.** And was there a period of time or did you come to learn
20 that any staff at DEA were not complying with that policy?

21 **A.** Yes.

22 **Q.** And can you explain what happened?

23 **A.** Staff put out an e-mail to distributors explaining that
24 a group of pharmacies were being cut off by another
25 distributor and -- just for information purposes.

1 **Q.** And do you know when or for how long that happened?

2 **A.** It wasn't too long. It was -- as soon as it was
3 brought to my attention, I had it stopped.

4 MS. SINGER: All right. I'm going to move into a
5 different subject area, Your Honor. Do you want to keep
6 going?

7 THE COURT: Let's try to keep going. I'd like to
8 get close to 3:30 so -- so the long haul to the end is not
9 too long.

10 MS. SINGER: Yeah.

11 BY MS. SINGER:

12 **Q.** Turning now to inspections, Mr. Rannazzisi, does DEA
13 periodically inspect defendants' distribution centers?

14 **A.** Yes.

15 **Q.** And how often do those inspections take place?

16 **A.** I can't tell you how long now, but when I was there, we
17 moved it from five years to three years. So, every three
18 years, there would be a cyclic investigation or inspection.

19 **Q.** And what's a cyclic investigation?

20 **A.** It just cycles through different areas -- different
21 registrants within a Field Division or a Field Office's area
22 of responsibility. They would cycle through every -- every
23 three years to make sure that all of their registrants,
24 their distributors, their manufacturers, whatever, have gone
25 through a full inspection.

1 Q. And I think you said that the frequencies of those --
2 frequency of those investigations changed during your
3 tenure; is that right?

4 A. Yeah. We -- we -- it was five when I got there and we
5 changed it to every three years after that.

6 Q. Why did do you that?

7 A. Because we wanted them in the facilities more.

8 Q. And who is "them"?

9 A. The inspectors, the diversion investigators.

10 Q. And how long does a cyclic investigation typically
11 last?

12 A. It depends on the size of the facility. It could be a
13 few days. It could be a few weeks.

14 Q. And during those cyclic inspections -- and I take it
15 among those inspections DEA performed during your tenure
16 were inspections of each of these defendants' distribution
17 centers; is that right?

18 A. Yes.

19 Q. And during those cyclic inspections did DEA review
20 defendants' policies and procedures for maintaining
21 effective controls against diversion?

22 A. Yes, they did.

23 Q. And did DEA look at customer due diligence files?

24 A. They can, yes. Yes.

25 Q. And are there -- are there limits to what DEA can

1 observe in inspecting a distributor's Suspicious Order
2 Monitoring System or compliance system when it's on-site?

3 **A.** Yes.

4 **Q.** And what are those limits?

5 **A.** You can review protocols and procedures, but to
6 actually see if the system works, you have to sit there with
7 the system day in and day out and watch how orders are being
8 processed out and identified and then suspicions resolved.
9 And they're not there full-time doing that. They're there
10 actually doing the inspection of the facility. So they look
11 at the processes and the procedures. They walk through how
12 -- how the systems work and then they move on.

13 **Q.** And in four days, or a few weeks, can an inspector
14 determine whether a Suspicious Order Monitoring System is
15 working effectively?

16 MR. SCHMIDT: Objection. I apologize. Objection,
17 foundation and calls for a legal opinion or an expert
18 opinion.

19 THE COURT: Well, I'm going to let him answer. I
20 think he's shown that he's got experience with the
21 inspections and I'll overrule the objection.

22 You can answer, Mr. Rannazzisi.

23 THE WITNESS: No. You -- you have to be at that
24 facility looking at that system and looking at the incoming
25 orders and the outgoing orders over an extended period of

1 time. So, they don't have the time during that inspection
2 to sit there and do that. It's -- it would take too much
3 time and it would be an extended period of time, so they
4 don't do that.

5 **Q.** And does your inspection tell you about a distributor's
6 Suspicious Order Monitoring System outside of the window of
7 time you're there?

8 **A.** No, it doesn't. It's just when we look at the
9 protocols and procedures they might review some suspicious
10 orders to see what they've captured. It's just while we're
11 there.

12 **Q.** And while DEA is conducting a cyclic inspection are you
13 doing things other than looking at the Suspicious Order
14 Monitoring System?

15 **A.** Yes, quite a bit.

16 **Q.** What other kinds of things are you looking at?

17 **A.** They have to look at recordkeeping. They have to do an
18 accountability audit. They have to do a full security sweep
19 and a security audit. They have to look to make sure that
20 the alarm systems are up to date, that the cage is compliant
21 with the federal -- with the Code of Federal Regulations,
22 that the vault is compliant with the Code of Federal
23 Regulations.

24 The security of the drugs on the floor. The security
25 of the drugs on the -- on the warehouse where the -- where

1 it's shipped out. How it's shipped out. How it's secure
2 before it gets shipped out.

3 All of that is part of the inspection process and the
4 audit takes a lot of time because they have to pick certain
5 ones and audit them to see if there's any shortages.

6 **Q.** And after DEA is finished with all of those tasks in
7 doing an inspection, does it convey its findings to the
8 distributor?

9 **A.** Yes. They should have a closeout after every
10 inspection. When I was there, that's what they did. They
11 had a closeout after every inspection.

12 **Q.** And what is a closeout?

13 **A.** They'd present their findings to the distributor.

14 **Q.** And is there any kind of written document that's
15 created in that process?

16 **A.** I believe there's a closeout for it, yes.

17 **Q.** Okay. And does that include positive and negative
18 observations?

19 **A.** Yes.

20 **Q.** Now, during your tenure as Deputy Assistant
21 Administrator did DEA determine in carrying out its
22 inspections of defendants' distributor -- distribution
23 centers that defendants failed to maintain effective
24 controls against diversion?

25 **A.** Could you repeat that again? I got failed to maintain

1 effective controls and I didn't get the first part.

2 **Q.** Yeah. In conducting inspections of defendants'
3 distribution centers during your tenure did DEA find the
4 defendants failed to maintain effective controls against
5 diversion?

6 **A.** Yeah. I don't recall. There were so many inspections
7 in the distributor -- the distributor population as a whole,
8 yes, I'm sure they have, but I just can't recall if these
9 three defendants had that type of, you know --

10 **Q.** And did your findings and visits -- and I'm sorry.
11 Beyond inspections did DEA visit distribution centers
12 outside of the cyclic investigations?

13 **A.** DEA can go in on a -- on a -- you know, could go in a
14 facility pretty much whenever they wanted. It's a question
15 of whether we've actually done an inspection within a year
16 and whether we executed a notice of inspection but, yes, DEA
17 could go into the facilities if need be.

18 **Q.** And did your findings during those inspections and
19 other visits inform the enforcement actions that DEA took
20 during your tenure as Deputy Assistant Administrator?

21 **A.** In some circumstances, yes.

22 **Q.** Now, in addition to inspections, did defendants meet
23 with DEA to discuss their compliance programs in other
24 settings?

25 **A.** I -- I don't -- I don't recall that.

1 **Q.** And do you know whether DEA provided feedback to these
2 defendants on the design of their Suspicious Order
3 Monitoring Systems?

4 **A.** They may have said the system -- generally what they
5 would say is the system looks -- looks like it's operational
6 or it looks -- it looks like it's operating appropriately.
7 That's about it. It can't -- it can't confirm it, but based
8 on the policies and procedures that they're looking at, they
9 would say it looks like it's operating appropriately.

10 **Q.** And did DEA have a policy or procedure of its own on
11 whether it could approve a defendant or distributor's
12 Suspicious Order Monitoring System?

13 **A.** No. There's no approval process. That's why they
14 would say it's operating satisfactorily. From what you've
15 shown me, it looks to be operating satisfactory, something
16 to that, but there was never an approval given for a
17 Suspicious Order Monitoring Program.

18 **Q.** And did DEA communicate to defendants that it could not
19 approve their Suspicious Order Monitoring Systems?

20 **A.** Yes.

21 **Q.** And do you know when those communications took place?

22 **A.** Just the letters to start off. The distributor
23 initiative, then the letters following the distributor
24 initiative. Then the Memorandums of Understanding and the
25 settlement agreements. They just continued on and on.

1 **Q.** Are you aware that during your tenure defendants used
2 thresholds as one -- as a way of identifying suspicious
3 orders?

4 **A.** I'm aware that the defendants used hard -- some of the
5 defendants used hard numbers during that time period, yes.

6 **Q.** And what do you mean by "hard numbers"?

7 **A.** Yeah. So, there would be a ceiling level or they would
8 create -- yeah. There would be a ceiling level where that
9 -- that would be the ceiling and then, anything above that
10 would be however they termed it, a breach, order of
11 interest.

12 **Q.** And do you know what defendants' thresholds were based
13 on during your tenure as Deputy Assistant Administrator?

14 **A.** I'm not sure.

15 **Q.** Do you know whether defendants used any kind of
16 multipliers of past orders as a vehicle for setting
17 thresholds?

18 MR. SCHMIDT: Objection, leading after the witness
19 has said he doesn't know.

20 THE COURT: Sustained.

21 BY MS. SINGER:

22 **Q.** To your knowledge, did DEA ever provide guidance to
23 defendants about whether they could use thresholds or
24 multipliers of orders to identify suspicious orders?

25 **A.** No. As far as I know from my time there, no. That

1 would have never -- that would not have occurred during my
2 time, yes.

3 **Q.** And did -- all right. Moving on to another topic --

4 THE COURT: This may be a good time for a break.

5 MS. SINGER: Yes, Your Honor.

6 THE COURT: We'll come back about 3:30. It looks
7 like we're at a convenient stopping point.

8 (Recess taken)

9 (Proceedings resumed at 3:31 p.m. as follows:)

10 THE COURT: All right, Ms. Singer.

11 BY MS. SINGER:

12 **Q.** All right, Mr. Rannazzisi, just a few more topics
13 this afternoon.

14 Now, I think you mentioned at the start of your
15 testimony that healthcare providers who prescribe controlled
16 substances are registered with the DEA; is that correct?

17 **A.** Yes.

18 **Q.** And based on your experience at DEA, were most
19 healthcare providers prescribing appropriately?

20 **A.** Yes.

21 **Q.** And have you offered any numbers as to what percentage
22 of the universe of prescribers you think are prescribing
23 appropriately and consistent with the law?

24 **A.** Yeah. We usually said 99 percent of the prescribers in
25 the United States are operating -- treating their patients

1 appropriately.

2 **Q.** And have you ever done the math to figure out how many
3 prescribers then aren't prescribing lawfully?

4 **A.** Do the math as far as -- I'm sorry.

5 **Q.** So how many -- that one percent, how many prescribers
6 is that?

7 **A.** Oh, depending on the population of prescribers at the
8 time. It's thousands, you know, over 10,000, 15,000.

9 **Q.** And in your experience, how much harm can 16,000
10 prescribers who are prescribing unlawfully do?

11 MS. WICHT: Objection, vague and lack of
12 foundation.

13 MR. NICHOLAS: And speculative and leading. I
14 object as well.

15 THE COURT: Sustained.

16 BY MS. SINGER:

17 **Q.** Can DEA take action to investigate or revoke the
18 registration of all of those prescribers?

19 **A.** It would -- that is a lot of prescribers and that would
20 be a lot of -- we -- no, we couldn't do that, not with the
21 manpower that we had at the time and now -- well, I don't
22 know what it is now, but when I was there, that would have
23 been an awful lot of work and quite a bit of -- I just don't
24 think we could have handled thousands of Orders to Show
25 Cause and Immediate Suspension Orders.

1 **Q.** And did DEA during your tenure take action against some
2 prescribers?

3 **A.** Of course we did, yes.

4 **Q.** And did defendants ever raise a concern with DEA, to
5 your knowledge, that they couldn't make judgments about
6 whether a prescriber was acting lawfully or whether a
7 prescription was valid?

8 **A.** That was a -- one of the statements that was made, yes.

9 **Q.** And what did, what did DEA tell them? What kind of
10 guidance did DEA provide?

11 **A.** We're not asking them to, to become doctors and figure
12 out what's legitimate and what's not. What we're asking
13 them to do is look at anomalies within their ordering
14 patterns and identify suspicious orders.

15 We never required them to look at what doctors were
16 doing, questioning a doctor's, a doctor's prescribing
17 habits. What we asked them to do is look at your
18 suspicious -- your pharmacy population, your customer
19 population, identify anomalies within that population,
20 ordering patterns, and then do your due diligence and see
21 why those anomalies exist.

22 **Q.** And I want to do just a few housekeeping items before
23 we turn to the next set of questions.

24 As part of your duties as Deputy Assistant
25 Administrator, did you testify before Congress?

1 **A.** Yes, I did.

2 **Q.** About how many times?

3 **A.** I seem to remember 33 as being the number.

4 **Q.** All right. I want to show you P-016726, please.

5 Actually, I'm sorry. That's -- I think it's P-01207.

6 MS. SINGER: May I approach, Your Honor?

7 BY MS. SINGER:

8 **Q.** Mr. Rannazzisi, do you recognize the -- recognize
9 the document that I've just shown you?

10 **A.** Yes, I do.

11 **Q.** And what do you recognize it as?

12 **A.** This is my testimony before House Judiciary,
13 Subcommittee on Crime, Terrorism & Homeland Security.

14 **Q.** And when you testified at that hearing, did you testify
15 in your personal capacity or as a representative of the DEA?

16 **A.** I was, I was the Drug Enforcement -- actually, I was
17 the administration representative. So I was representing
18 DOJ and the administration.

19 **Q.** And when you testified at that hearing, were you
20 conveying the official position of the DOJ to Congress?

21 **A.** It would be the official administration position
22 through the DOJ.

23 **Q.** And does this reflect the remarks you gave as your
24 testimony?

25 **A.** Yes.

1 MS. SINGER: We move to admit P-01207, Your Honor.

2 THE COURT: Any objection?

3 MS. WICHT: I think it's hearsay, Your Honor.

4 It's a prior out-of-court statement by the witness. I don't
5 know for what purpose it's being offered. Yes, we object.
6 It's hearsay.

7 MS. SINGER: So, Your Honor, I would submit that
8 this is a public record under F.R.E. 803(8)(A)(i). It is a
9 record or statement of a public office that sets out the
10 office's activities.

11 Also under 803(8)(A)(iii), the record statement of a --
12 oops, I need to set one other foundation element if you need
13 me to go there.

14 And I would also cite, Your Honor, *SEC vs. Pentagon*
15 *Capital Management*, 722 F.Supp. 2d 440, a case from the
16 Southern District of New York finding congressional
17 testimony from the SEC Director of the Division of
18 Enforcement was a public record and admissible pursuant to
19 F.R.E. 803.

20 THE COURT: It's admitted.

21 BY MS. SINGER:

22 Q. All right. One other document.

23 All right. I'm going to show the witness, with the
24 Court's permission, P-16726.

25 Mr. Rannazzisi, do you recognize that document?

1 **A.** Yes.

2 **Q.** And what do you recognize that document to be?

3 **A.** This is testimony before the International Narcotics
4 Control Caucus in 2012.

5 **Q.** And is that testimony that you gave to Congress?

6 **A.** Yes.

7 **Q.** And when you testified at that hearing, did you testify
8 in your personal capacity or as a representative of DEA?

9 **A.** It's always as a representative of the administration
10 DOJ and DEA.

11 **Q.** And when you testified at that hearing, were you
12 conveying the official position of the DEA to Congress or
13 the administration?

14 **A.** Yes.

15 **Q.** Did you -- does that document represent the testimony
16 that you gave?

17 **A.** Yes.

18 MS. SINGER: Your Honor, I would move to admit
19 P-016726, please.

20 THE COURT: Ms. Wicht.

21 MS. WICHT: I would make the same objection, Your
22 Honor, and I don't -- we'd make the same objection.

23 THE COURT: All right. Overruled. It's admitted.

24 MR. SCHMIDT: Your Honor, obviously I take it we
25 can still object to individual use of these documents if

1 they're just kind of putting them in the record.

2 THE COURT: Yes.

3 MR. SCHMIDT: Thank you.

4 BY MS. SINGER:

5 **Q.** Mr. Rannazzisi, on P-01207, the first testimony you
6 looked at, may I ask you to turn to Page 6 under the P
7 number which is Page 5 of the document page number?

8 **A.** Okay.

9 MS. SINGER: And can we put that up on the screen,
10 please?

11 BY MS. SINGER:

12 **Q.** Mr. Rannazzisi, while we get that up on the screen,
13 would you mind just reading the beginning of that
14 paragraph, please?

15 **A.** Which paragraph?

16 **Q.** I'm sorry. That would help. "The sheer volume of
17 controlled substances." It's the second full paragraph.

18 **A.** "The sheer volume of controlled substances being
19 illicitly dispensed anonymously over the internet
20 contributes significantly to other downstream methods of
21 diversion; examples, children and young adults getting
22 controlled substances from the medicine cabinet or family
23 and friends. While studies such as the national survey on
24 drug use and health indicate that only a small percent and,
25 less than one percent, get controlled pharmaceuticals via

1 the internet, the majority obtaining substances illicitly
2 from family and friends or by stealing them from the
3 medicine cabinet. They typically acquire less pills than on
4 the internet. By contrast, DEA investigations clearly
5 reveal that individuals illicitly ordering via the internet
6 frequently receive 100 to 120 pills at a time. Thus, those
7 who receive their drugs via rogue internet pharmacies are
8 netting more pills than they would from friends or the
9 family medicine cabinets. Our investigations have led us to
10 believe that the internet is one of the major upstream
11 sources. For example, a 2006 DEA investigation revealed
12 that one rogue internet pharmacy distributed in excess of
13 15 million hydrocodone tablets in a single year."

14 **Q.** And does that reflect the official testimony that you
15 provided to Congress?

16 **A.** On behalf of the administration, yes.

17 **Q.** And is this statement also true of other sources of
18 diversion besides the internet such as pill mills?

19 MR. SCHMIDT: Objection, vague. I'm sorry.
20 Objection, vague and also calls for an expert opinion.

21 THE COURT: I'll overrule the objection.

22 THE WITNESS: Yes, any type of large-scale
23 diversion such as pill mills would be in the same, the same
24 place as this.

25 BY MS. SINGER:

1 **Q.** All right. You can put those testimonies aside. I
2 want to show you P-42383.

3 I think we're going out with a bang, or at least a big
4 mess, Your Honor.

5 May I approach?

6 THE COURT: Yes.

7 BY MS. SINGER:

8 **Q.** I will try not to shower you with paper, Mr.
9 Rannazzisi.

10 Mr. Rannazzisi, I would direct you to the first page
11 after that cover email. Do you recognize this document?

12 **A.** Yeah. This is a PDAC, or Pharmacy Diversion Awareness
13 Conference presentation.

14 **Q.** And do you recognize this as an official DEA
15 presentation that was provided at that conference?

16 **A.** Yes.

17 **Q.** And what is the date of this presentation?

18 **A.** March 2nd and 3rd, 2013.

19 **Q.** And do you know whether this presentation -- I'm sorry.
20 I may have asked this -- was part of your -- nevermind. I'm
21 sure I asked that. We're just going to look at one page of
22 it --

23 **A.** Sure.

24 **Q.** -- which is 745 which is the Bates number. It's Bates
25 number, not P number.

1 MR. SCHMIDT: We offer two objections to this,
2 Your Honor.

3 The first is this document is hearsay, and using it for
4 this purpose is hearsay. And the second is they appear to
5 be trying to elicit a gateway opinion from someone who's not
6 an expert and using a slide that someone else used for that
7 purpose.

8 THE COURT: Do you want to respond to that?

9 MS. SINGER: Sure, Your Honor. This is a slide
10 that represents the DEA's not expert opinion but its
11 practical experience as a law enforcement agency as to what
12 the agency observed about the use and migration or
13 transition from prescription opioids to heroin, which is
14 something that it determined in carrying out its law
15 enforcement function.

16 THE COURT: You're offering one page of this?

17 MS. SINGER: Just one page and just for the
18 witness's testimony. I'm not going to move it --

19 THE COURT: What page is it?

20 MS. SINGER: It's Bates Number 745, Your Honor.
21 We can also put it up on the screen, I hope, if you just
22 want to take a look at it that way.

23 THE COURT: I'm having trouble finding the page
24 number. 745?

25 MS. SINGER: Yeah. I assume it's on your screen

1 as well, Your Honor.

2 MR. SCHMIDT: It's Page 120 of the exhibit.

3 THE COURT: It's Page --

4 MR. SCHMIDT: Page 120 of the exhibit, Your Honor.

5 THE COURT: Oh, okay. Thank you. All right.

6 I've got it.

7 What's the purpose of this? Why are you offering it?

8 MS. SINGER: I just wanted to ask the witness to
9 explain what this slide and DEA's official presentation to
10 industry offer. And I would use it, Your Honor, as notice
11 to industry about what was happening with prescription
12 drugs.

13 MR. SCHMIDT: So that highlights our objection.
14 Notice to industry has nothing necessarily to do with the
15 defendants in this case. It was a presentation by someone
16 other than him where I suspect he can't even say what was
17 said about the slide or whether it was actually used in this
18 massive presentation deck. And it still runs into this
19 problem we're very clearly trying to elicit an expert
20 opinion on gateway.

21 MR. NICHOLAS: The one thing I'll add is that it
22 doesn't appear that, that my client, for example, attended
23 this conference. So in terms of the notice point, I'm not
24 sure this gets it done.

25 MS. WICHT: I don't think there's any foundation

1 about any defendant attending the conference, Your Honor, at
2 this point.

3 THE COURT: Yeah. I'm going to sustain the
4 objection to the exhibit. You can ask him questions about
5 that general subject area and we'll see where we go with
6 that.

7 BY MS. SINGER:

8 Q. So, Mr. Rannazzisi, during your tenure at DEA, both
9 before and during your service as Deputy Assistant
10 Administrator, did you have a chance to form any
11 observations with respect to use of opioids and its
12 relationship to heroin?

13 MR. SCHMIDT: And, Your Honor, this is pure expert
14 testimony. They have experts to cover this. Mr. Rannazzisi
15 is not an expert on this. I don't believe this was ever
16 covered at his trial deposition. So it's outside the scope
17 as well as improper expert testimony.

18 MR. NICHOLAS: Outside the scope is what I was
19 going to say.

20 THE COURT: I'll sustain the objection.

21 BY MS. SINGER:

22 Q. Mr. Rannazzisi, in your experience with law
23 enforcement, and I'll ask one more question on this, did
24 you observe that prescription -- that, that heroin users
25 had often started as prescription opioid users and/or --

1 I'm sorry. Let me rephrase. I'm sorry. I'll take one
2 more crack at this.

3 Did you observe that DEA's enforcement activities
4 transitioned to heroin as a result of the diversion of
5 prescription opioids?

6 MR. NICHOLAS: I would interpose the same
7 objection.

8 MR. SCHMIDT: Same, scope and expert opinion.

9 THE COURT: I'm going to sustain the objection,
10 Ms. Singer.

11 MS. SINGER: We'll move on.

12 BY MS. SINGER:

13 **Q.** Mr. Rannazzisi, for our last substantive topic I
14 want to turn to quota and it's something I think we've
15 talked about for a while.

16 Can you briefly at a 20,000-foot level explain to the
17 Court how quota for controlled substances works?

18 **A.** The quota is an estimate of the total amount of a
19 specific substance that can be made in the United States.
20 It's governed by 21, U.S.C., 826 which provides a road map
21 of what we need to include in our assessment in order to
22 establish that quota.

23 It's -- during my time, it was only established by a
24 base code of drug. And what that means is we'll establish
25 quota for hydrocodone. That's it. But not by dosage units,

1 but by the amount of powder, the amount of drug that's
2 actually being made.

3 Now, Congress gave us many different things to look at
4 to establish this quota, knowing that the quota was
5 necessary, not only because, one, it was required under,
6 under UN treaties, but the second reason was Congress wanted
7 to ensure that there was enough drug in the system to meet
8 the legitimate medical, scientific, and industrial needs of
9 the country. It's in 826.

10 What Congress, and what we're -- our charge was under
11 826 is to ensure that legitimate patients were getting their
12 medication and not having shortages so a patient would do
13 without. That was the whole basis of the quota.

14 The problem with quota is there's so many different
15 things involved that you have to look at not just how much
16 is being allowed to be made for patients, but also how much
17 is being allotted for research and development, for
18 validation studies, for export, for all those things that
19 are necessary for scientific and industrial purposes. That
20 quota will never -- would never get to a patient.

21 So there's two parts to quota. There's a first part
22 where it's the amount of drug that would go to a patient, go
23 to patient population. And the second part of quota is the
24 amount of drug that goes to research development, export,
25 validation, scientific and medical needs. That's how quota

1 is generally set up. But it's -- we're required to follow
2 the road map that Congress gave us in 826.

3 **Q.** All right. I was going to put up a slide, but I don't
4 know that you need to see the statute, Mr. Rannazzisi.

5 Did you take -- I'm sorry. What was your role at DEA
6 when you were Deputy Assistant Administrator with respect to
7 setting quota?

8 **A.** I oversaw the quota unit, the UN reporting quota unit.
9 And that was a group of scientists. And those scientists
10 day in and day out would look at quota requests and look at
11 the available materials, what both the manufacturers
12 requested and what we could find, and then make a
13 determination if their quota request was in line with how
14 much need there would be.

15 Now, my job was to look at what they did and eventually
16 sign off on their letters, but also sign off on the overall
17 aggregate quota so the administrator could certify it and
18 publish it.

19 **Q.** And in your role in overseeing the quota section and
20 making recommendations to the administrator --

21 **A.** Deputy administrator.

22 **Q.** -- deputy administrator, did you also take diversion
23 into account?

24 **A.** Yes. There's, there's a specific provision in the 826
25 that allows us to look at other things, and we did take

1 diversion into account.

2 **Q.** Now, did quota for oxycodone and hydrocodone increase
3 significantly during your tenure?

4 **A.** Absolutely.

5 **Q.** And why was that?

6 **A.** Because part of the quota involves the amount of
7 disposal or the amount that's being, that's being either
8 prescribed out or used in hospitals. And as that number
9 kept going up, we would have to adjust the quota every year
10 to ensure that there was enough quota for patients.

11 So the way it worked was if, if more prescriptions were
12 going out of pharmacies, if more patients in hospitals were
13 getting more drug, that quota was going to increase because
14 we have to meet the needs of the patient population.

15 But in the same token, we also had during that time
16 period research on certain drugs, research on new
17 formulations of, say, hydrocodone or oxycodone. And the
18 researchers, the companies that were conducting the
19 research, that were conducting validation, they had to have
20 quota.

21 Now, that quota may never, ever see a patient, but it
22 had to be given out because if we can't give them the quota
23 for, for that research and development, for the industrial
24 use, for the export, if they can't get that, then they can't
25 continue their research.

1 So we had to make sure that there was enough in place
2 to take care of the patients, but then also to make sure
3 there was enough to handle the research and development and
4 all the other things that go on with scientific research
5 regarding specific drug products.

6 **Q.** So, Mr. Rannazzisi, as the opioid epidemic and opioid
7 diversion grew, why didn't DEA lower quota?

8 **A.** You can't just lower quota. It, it doesn't work that
9 way. And I know people have said this over and over again.
10 Quota -- it's a scientific and mathematical exercise to
11 ensure that there's enough drug in the system.

12 I always think of it this way. If you have 100 people
13 and all of those people are trying to get oxycodone and some
14 of them are, are drug seekers who shouldn't have it and some
15 of them are legitimate patients that need it, maybe they're
16 palliative care, maybe they're chronic pain, but they need
17 that drug, the quota is established so they will get their
18 drug.

19 But if I come in and say, you know what, I'm just going
20 to cut it by 20 percent, then that's 20 percent less but
21 that patient -- the patient population and those drug
22 seekers are competing for now 20 percent less. And that's
23 how shortages occur.

24 I can't do anything about the people who are seeking
25 drugs other than fine them and either get them help or put

1 them in jail. But I have to maintain enough drug in the
2 system so those legitimate patients, palliative care,
3 hospice, end of life care, those patients have their
4 medication because if I don't do that, I'm not meeting my
5 charge under 826. And I'm not doing the patients any good
6 either.

7 And, and that's my problem. I'm, I'm -- we're
8 balancing -- we're doing this balancing act to ensure that
9 there's enough drug in the system, but not enough drug where
10 it could sit on a shelf somewhere so somebody could break
11 into a facility and steal it. And that's the problem.

12 And we didn't even talk about inventory because 826
13 requires us to give a percentage of inventory allotment in
14 addition to the quota.

15 So there is so many different dynamics with quota. So
16 when I hear people say just reduce it by 20 percent, well,
17 we might reduce it by 20 percent, but if we don't reduce the
18 amount of patients that are actually seeking -- that need
19 that drug by 20 percent, then, then we're going to have a
20 shortage.

21 And a perfect example of that, if I may, a perfect
22 example of that is hydrocodone. Hydrocodone at one point in
23 time was the number one drug in the United States. It
24 wasn't the number one controlled substance. It was the
25 number one drug in the United States. More people had

1 prescriptions of hydrocodone than any other drug.

2 We knew that was a problem between the internet and the
3 pill mills and we decided to make a change. We went through
4 the controlled substances. We decided we were going to take
5 hydrocodone and down-schedule it from Schedule III to
6 Schedule II.

7 Now, that's a very important -- that's a very important
8 distinction. A Schedule II controlled substance, there is
9 no refills. You have to give a written prescription. A
10 Schedule III controlled substance, you have to go -- you
11 could have five refills, you don't need a written
12 prescription. You could call it in.

13 When we made that change in 2014, by 2017 hydrocodone
14 had decreased dramatically. The number of prescriptions
15 went down. It, it was reduced from the number one drug to
16 way down the list.

17 Now, why was that? Because we required the doctors to
18 change the way they did business with hydrocodone. They
19 could no longer call it in, no refills. They had to write
20 that prescription.

21 And that caused the quota to decrease dramatically.
22 Within three years, it went down almost 33 percent or
23 something like that.

24 That's how quota works. It's based on need. It's
25 based on the patient need, not the, not the people who are

1 drug seekers because they'll get the drug at the expense of
2 legitimate patients if we can't put enough drug in the
3 system.

4 So when we say let's just cut it by 20 percent, quite
5 frankly, that's a very ignorant statement.

6 **Q.** Mr. Rannazzisi, can you use quota to direct drugs to
7 legitimate patients versus drug seekers, as you say? Does
8 quota let you do that?

9 **A.** I'm sorry. Could you repeat that one more time?

10 **Q.** Can you use -- can -- does the quota system let you
11 direct controlled substances to legitimate patients rather
12 than drug seekers?

13 **A.** No, it doesn't. The, the, the quota provision of the
14 Controlled Substances Act just says that we must make sure
15 that there's enough quota in the system, enough base code
16 drug in the system to, to, for legitimate medical,
17 scientific, and industrial needs of the country, which means
18 legitimate patients as the medical portion of that.

19 **Q.** And, so, if it's not quota, what in your experience
20 does work to keep drug diversions down and keep drugs out of
21 the hands of drug seekers?

22 MR. SCHMIDT: Expert opinion, outside the scope of
23 the MDL deposition.

24 THE COURT: Overruled. I think he can answer that
25 based upon his experience.

1 THE WITNESS: Can you repeat that? I want to make
2 sure I get it right.

3 BY MS. SINGER:

4 Q. In your experience -- if it's not quota, what in
5 your experience works to prevent diversion and keep
6 drugs out of the hands of drug seekers?

7 A. Compliance with the Controlled Substances Act at every
8 level of the distribution chain, making sure that, you know,
9 there's, there's abatement of drugs going to pharmacies that
10 shows suspicious ordering patterns. That's, that's what
11 stops -- that's what stops drug-seeking behavior because if
12 they can't get the drug, if they can't go into the pharmacy
13 to get the drug, they're shut off.

14 Q. Okay. All right. Let's move on and wrap up the last
15 stop on our road trip.

16 Mr. Rannazzisi, can you remind us how long did you
17 serve as Deputy Assistant Administrator?

18 A. In an acting capacity from July of 2005 to January of
19 2006. And then I took over the Office of Diversion Control
20 in January of 2006.

21 Q. And how long in total were you at the DEA?

22 A. 29 plus years.

23 Q. What kept you at DEA throughout your career?

24 A. I think the reason I stayed was because it was my
25 ability to serve, and seeing, seeing what drugs did to

1 people, you know, in my neighborhood, you know, people I
2 went to school with, people I went to college with. It, it
3 just was -- just -- the way I thought I could serve was to
4 do this job. And, you know, I stayed with it for 29 plus
5 years.

6 **Q.** And over the course of your tenure, particularly as
7 Deputy Assistant Administrator, did your relationship with
8 distributors change, with these defendants in particular?

9 **A.** I don't know if the relationship changed. My
10 relationship was the regulator. So I had to regulate that
11 community of registrants. Did it change? Yeah. They, they
12 didn't want to -- they didn't want --

13 MR. SCHMIDT: He's literally giving an opinion
14 about our client's state of mind that he has no basis to
15 give.

16 THE COURT: Sustained.

17 BY MS. SINGER:

18 **Q.** So can you answer the question, Mr. Rannazzisi,
19 with respect to what you observed about your
20 relationship with these defendants?

21 **A.** As, as time went on, it got more adversarial.

22 **Q.** And did you, did you ever say publicly that you were at
23 war with industry?

24 **A.** Yes, I did.

25 **Q.** And what did you mean?

1 **A.** I think I said that right after the, the Cardinal -- I
2 think it was right after we executed the 2012 Orders to Show
3 Cause -- the Orders to Show Cause and Immediate Suspension
4 Order on Cardinal and CVS. And, and that came about because
5 I was called over to the department and they were just
6 trying to circumvent me and what we were trying to do.

7 MR. SCHMIDT: Your Honor -- go ahead. Sorry.

8 MS. WICHT: I'll object to the witness purporting
9 to say what the company was intending to do.

10 MR. SCHMIDT: Yeah, same objection. I think the
11 witness obviously has strong views, but they don't form
12 facts.

13 BY MS. SINGER:

14 **Q.** Mr. Rannazzisi, I know the Judge directed us to
15 stick to the facts. So what did you, what did you
16 observe?

17 **A.** I think I observed that they were not complying and
18 they continued to not comply. And that's what I observed.
19 And, so, we just continued to do what we were doing, which
20 was enforcing the law.

21 THE COURT: Ms. Wicht.

22 MS. WICHT: Objection to the legal conclusion,
23 Your Honor.

24 THE COURT: I'll overrule the objection.

25 BY MS. SINGER:

1 **Q.** And, so, Mr. Rannazzisi, when you said you were,
2 you were at war with industry, who started the war from
3 your perspective?

4 MS. WICHT: Objection, Your Honor.

5 MR. SCHMIDT: Objection, Your Honor. The
6 witness --

7 THE COURT: Yeah, this is, this is -- this line
8 has gone far enough, Ms. Singer. You made your point and
9 I'll sustain that objection.

10 BY MS. SINGER:

11 **Q.** Okay. What have you done since you left the DEA?

12 **A.** I'm, I'm a consultant for other states that were, that
13 are taking action against the opioid manufacturers and
14 distributors.

15 **Q.** And is that for state government?

16 **A.** Yes.

17 **Q.** And do you do anything in addition to your consulting
18 or expert work?

19 **A.** I, I -- well, I haven't in a long time because of
20 COVID, but I used to speak for different groups.

21 **Q.** What kind of groups?

22 **A.** It depends. Some, some paid me. Others I did for
23 free. If it was a law enforcement group or a group whose
24 lost loved ones, you know, anti-addiction group, a support
25 group, those, those are all -- regulators, state regulators,

1 state regulators, continuing education, I did all those for
2 free. I just asked them to pay my way out and back.

3 **Q.** And I take it you have been paid for your work as an
4 expert consultant to states in the opioid litigation?

5 **A.** Yes.

6 **Q.** And how much have you been paid?

7 **A.** Since 2017, I think it was July of 2017, about
8 \$860,000.

9 **Q.** And how does that compare with the salary on an annual
10 basis that you made in law enforcement?

11 **A.** Law enforcement my last year, last two or three years I
12 made about \$180,000 a year.

13 **Q.** Now, after you left the DEA, did you also agree to be
14 interviewed by the news show *60 Minutes*?

15 **A.** Yes, I did.

16 **Q.** And were you interviewed by the *Washington Post*?

17 MR. SCHMIDT: Objection, Your Honor, relevance.

18 THE COURT: What's the relevance of his interview
19 with *60 Minutes*?

20 MS. SINGER: Going to this witness's motives for
21 being here.

22 MR. SCHMIDT: He's explained his motives for being
23 here. He's got a bias. He said he's at war with us. The
24 fact that he went and did interviews doesn't speak to that,
25 Your Honor.

1 MS. SINGER: I think he didn't testify to his bias
2 as being at war with you. I think he testified to your
3 non-compliance.

4 THE COURT: I'm going to sustain the objection on
5 relevance grounds.

6 MR. IRPINO: Your Honor, Anthony Irpino on behalf
7 of Cabell County. If they're not going to go into it on
8 cross, then that's fine. If they're not going into *60*
9 *Minutes*, they're not going into the *Washington Post*, then
10 that's fine.

11 THE COURT: Well, we'll see where we go. I can't
12 prejudge that at this point, but I'm sustaining the
13 objection that was made now.

14 MS. SINGER: All right. Your Honor, may I have
15 just a moment, please?

16 THE COURT: Yes.

17 MS. SINGER: Thank you.

18 (Pause)

19 MS. SINGER: Your Honor, I have nothing further
20 for the witness.

21 THE COURT: All right, Mr. Schmidt.

22 CROSS EXAMINATION

23 BY MR. SCHMIDT:

24 **Q.** Good afternoon, Mr. Rannazzisi.

25 MR. SCHMIDT: May I proceed, Your Honor?

1 THE COURT: Yes, you may.

2 THE WITNESS: Good afternoon.

3 BY MR. SCHMIDT:

4 Q. Just to start at the basics, the DEA is the federal
5 agency charged with overseeing the entire closed system
6 of distribution; correct?

7 A. That is correct.

8 Q. They're the gatekeeper of that system; correct?

9 A. They are there to oversee that the system works.

10 Q. They're the ones who choose whether to open that gate
11 and allow entities to be part of the closed system; correct?

12 In that sense, they're the gatekeeper; correct?

13 A. We register people, yes, to be in the closed system,
14 yes.

15 Q. And you can't be in the closed system if the DEA
16 doesn't open that gate through registration; correct?

17 A. For the most part, that's correct, yes.

18 Q. Now, just because you touched on this a couple times, I
19 want to just ask you some questions about resources at the
20 DEA.

21 While you were head of the Office of Diversion Control,
22 you oversaw approximately 300 personnel. True?

23 A. In my office, yes.

24 Q. You had an annual budget of nearly 350, five
25 zero, million; correct?

1 **A.** That's correct.

2 **Q.** And that was annual; correct?

3 **A.** Yes.

4 **Q.** There were nearly 1,000 field personnel to whom you
5 provided strategic direction; correct?

6 **A.** That's correct.

7 **Q.** We've heard a little bit about this, but I'll ask you
8 what this is. What's a Tactical Diversion Squad?

9 **A.** I'm sorry. What was the question?

10 **Q.** What is a Tactical Diversion Squad, or a TDS it's
11 sometimes called?

12 **A.** A Tactical Diversion Squad is basically a diversion
13 Task Force. It contains both DEA diversion investigators,
14 special agents, and state, local police officers who form a
15 group to run cooperative investigations on anybody, anybody
16 in that system, anybody in the closed system.

17 **Q.** And by the time you left DEA, you had somewhere on the
18 order of 66 of these Tactical Diversion Squads; correct?

19 **A.** Approximately, yes.

20 **Q.** Now, let me focus on your role. You gave some very
21 broad views, and I want to focus on your relevant time
22 period as it relates to distributors. Okay?

23 You were head of the Office of Diversion Control for 10
24 years; correct?

25 **A.** Yes.

1 Q. That was from July, 2005, to October, 2015; correct?

2 A. Yes.

3 Q. And that was through some of the very worst of the
4 opioid crisis; correct?

5 A. That is correct.

6 Q. In terms of your role prior to that time, and even
7 during that time, we've heard about distributor meetings
8 that happened in 2005. Do you remember talking about those
9 distributor meetings?

10 A. Yes.

11 Q. You did not attend any of those with McKesson,
12 Cardinal, or ABDC. True?

13 A. No, I attended that second meeting with McKesson.

14 Q. Okay. Let's cull up the July 16th, 2020 -- let me just
15 give you -- ask it one more time. You did not attend the
16 distributor briefings for McKesson, Cardinal, or ABDC that
17 happened in 2005; correct?

18 A. In 2005, that's correct.

19 Q. Okay. Prior to that time, prior to the time you came
20 into your role in 2005, you did not regularly interact with
21 wholesale distributors. True?

22 A. That's correct.

23 Q. Prior to that time -- actually, throughout your time,
24 you did not perform any sort of regulatory inspection of
25 distribution centers; correct?

1 **A.** No, that's not correct. I was a diversion investigator
2 in the '80s, late '80s. So I did do regulatory inspections
3 on distributors and manufacturers.

4 MR. SCHMIDT: Could we cull up April 26th, 2019,
5 Page 229, lines 17 to 22.

6 BY MR. SCHMIDT:

7 **Q.** Do you remember being deposed --

8 **A.** Yes.

9 **Q.** -- in April of 2019?

10 **A.** Yes.

11 **Q.** Let's go to Page 229, please.

12 And do you see on line 17 you were asked: "And you
13 didn't perform any sort of regulatory inspections of
14 distribution centers; correct?"

15 And do you see your answer: "That -- that's correct."

16 Did I read that correctly?

17 **A.** That's what it says, yes.

18 **Q.** Were you trying to testify truthfully in that
19 testimony?

20 **A.** That's correct.

21 **Q.** Prior to this time period in 2005, you didn't review
22 what you call excessive purchase reports; correct?

23 **A.** Is it possible -- I didn't get to see what was before
24 those when I made that statement.

25 **Q.** In the interest of time, I'm going to try to ask you my

1 next question unless the Judge directs me to show it to you.
2 I'll leave that for counsel for the plaintiffs.

3 MR. ACKERMAN: Your Honor --

4 MR. SCHMIDT: We have a lot to cover.

5 MR. ACKERMAN: I'm sorry. I thought you were
6 done.

7 MR. SCHMIDT: That's okay.

8 MR. ACKERMAN: I do believe that the question
9 before clarifies that question and in the interest of
10 completeness should be shown.

11 MR. SCHMIDT: I don't think it does, Your Honor.
12 The question before was about regularly interacting with
13 wholesale distributors in a certain period --

14 MR. ACKERMAN: As a time frame.

15 THE COURT: Let's move on.

16 MR. SCHMIDT: Okay.

17 BY MR. SCHMIDT:

18 **Q.** You did not review what you refer to as excessive
19 purchase orders prior to your position in Diversion
20 Control in 2005; correct?

21 **A.** No. I -- again, back in the '80s we had excessive
22 purchase reports. They used to come in boxes.

23 **Q.** Let me try to narrow it. From 1988 to 2004 you did not
24 review those excessive purchase reports; correct?

25 **A.** That's correct, yes.

1 **Q.** From that time period, you didn't provide guidance on
2 suspicious order reporting, 1988 through 2004; correct?

3 **A.** That's correct.

4 **Q.** Now, I want to touch on some of the topics that you've
5 covered. And first you talked about internet pharmacies.
6 Those arose in the early 2000s; correct?

7 **A.** Yes.

8 **Q.** And the shipments that you talked about from the
9 defendants occurred before 2007; correct? The ones focused
10 on Florida?

11 **A.** Yes.

12 **Q.** In 2008 Congress passed a statute that pretty much shut
13 down most of the internet pharmacies; correct?

14 **A.** Yes, Ryan Haight.

15 **Q.** And there have been no shipments by defendants to the
16 internet pharmacies you described for over a dozen years;
17 correct?

18 **A.** Since Ryan Haight, I'm not aware of any shipments.

19 **Q.** Okay. And that's over a dozen years; right?

20 **A.** Yes.

21 **Q.** You knew that each defendant changed their policies of
22 suspicious order monitoring policies as a result of the
23 guidance DEA gave them during that time period, that
24 2006-2007 time period?

25 **A.** I would, I would hope so.

1 **Q.** Do you know that, sir, given the testimony you've
2 given? Did you check that or do you know that?

3 **A.** Based on the, based on the Settlement Agreements and
4 what they purported, yes, they were supposed to change -- I
5 assume they did.

6 **Q.** Do you know if they did given the testimony you've
7 given here today? Did you look at that when you were at
8 DEA?

9 **A.** Which part of the --

10 **Q.** If they changed their policy, sir.

11 **A.** But which part of the policy? The policies pertaining
12 to the internet or policies pertaining to suspicious order
13 monitoring in general?

14 **Q.** The Suspicious Order Monitoring System, sir. Do you
15 know if they changed it from your work at DEA?

16 **A.** I believe they did change it, yes.

17 **Q.** Thank you. Do you know of any internet pharmacies
18 during that window of time you were talking about that were
19 located in Huntington or Cabell County?

20 **A.** I'm not aware of an internet pharmacy operating in
21 Huntington or Cabell County.

22 **Q.** The ones you were talking about were located in
23 Florida; is that right?

24 **A.** Florida and other places in the United States.

25 **Q.** You know that those internet pharmacies while

1 defendants supplied them were licensed or registered,
2 rather, by the DEA; correct?

3 **A.** Could you repeat that?

4 **Q.** Those internet pharmacies, while defendants supplied
5 them, were registered by the DEA; correct?

6 **A.** That's correct.

7 **Q.** And when DEA raised concerns about their volumes, DEA
8 knew those volumes from the ARCOS data; correct? You
9 testified to that; right?

10 **A.** Yes, retrospectively we did, yes.

11 **Q.** And that ARCOS data came from the distributors;
12 correct?

13 **A.** The ARCOS data did come from distributors, yes.

14 **Q.** They provided the data that allowed the DEA to flag
15 those concerns; correct?

16 **A.** They provided the data, yes.

17 **Q.** And did you know that they actually submitted
18 suspicious orders for those pharmacies?

19 **A.** I'm not aware of suspicious orders being submitted for
20 those pharmacies, no.

21 **Q.** Did you undertake to search for that?

22 **A.** Yes, we did.

23 **Q.** Okay. Did you personally?

24 **A.** I -- well, personally, no, but the staff did, yes.

25 **Q.** Do you know that the defendants cut off those internet

1 pharmacies, but that they remained open for a period of time
2 and registered for a period of time with the DEA after the
3 defendants cut them off?

4 MS. SINGER: Objection, Your Honor, misstates the
5 witness's testimony.

6 MR. SCHMIDT: I didn't state the witness's
7 testimony, Your Honor.

8 THE COURT: Yeah, overruled.

9 BY MR. SCHMIDT:

10 Q. Do you need my question again?

11 A. Yes, I'm sure there was a lag time between the time we
12 shut those pharmacies off because the administrative process
13 takes time.

14 Q. Okay. And during that time, they continued to provide
15 pills into the community; correct?

16 A. Well, not if you shut them off.

17 Q. Not from us, from other distributors when they remained
18 open. You know that happened?

19 A. No, I don't know that it happened.

20 Q. Okay. Well, let's take a look at that.

21 A. Okay.

22 Q. I want to start by talking about McKesson and I want to
23 show you a document that we didn't look at in your direct
24 exam but that I'd like to look at with you.

25 A. Okay.

1 MR. SCHMIDT: May I approach, Your Honor?

2 THE COURT: Yes.

3 MR. SCHMIDT: Thank you.

4 BY MR. SCHMIDT:

5 Q. Do you remember that January 23rd, 2006, memo that
6 summarized the meeting between McKesson and DEA that you
7 talked about on direct examination regarding the
8 Lakeland pharmacies?

9 MS. SINGER: Your Honor --

10 Mr. Schmidt, I don't mean to interject, but we don't
11 have copies of the document.

12 MR. SCHMIDT: We passed out this document and
13 marked it into evidence. It's P --

14 MR. ACKERMAN: Can we just get a P number?

15 MR. SCHMIDT: Yeah. It's one you used for
16 probably half an hour. It's P-9116.

17 BY MR. SCHMIDT:

18 Q. Do you remember being asked about P-9116 which was
19 a January 23rd DEA memo talking about the January 3rd
20 meeting between McKesson and DEA?

21 A. Yes.

22 Q. Do you know that McKesson followed up on that meeting
23 in writing?

24 A. I don't know that for sure, no.

25 Q. You don't know if they wrote a letter directly to you

1 personally?

2 **A.** I don't recall a letter being written.

3 **Q.** Okay. I'm passing you a copy of what's been marked
4 Defense West Virginia 1557. This is a letter from
5 January 18th, 2006, from Mr. Paul Julian at McKesson to you.
6 Do you see that?

7 **A.** Yes.

8 **Q.** And do you see that it says, "This letter is in
9 response to recent meetings between McKesson Corporation and
10 the Drug Enforcement Administration over concerns about
11 distribution of certain controlled substances from our
12 Lakeland, Florida distribution center." Do you see that?

13 **A.** Yes.

14 **Q.** And this is just a few weeks after that meeting we were
15 just referencing, correct, between DEA and McKesson?

16 **A.** Yes.

17 **Q.** Let's go to the second page of this letter, please.

18 And if you look at the second paragraph do you see that
19 it tells you McKesson has distributed educational
20 information on internet pharmacies to operations and sales
21 personnel?

22 **A.** Yes.

23 **Q.** And then further down, a couple sentences down he says
24 McKesson is in the process of revising its procedures to
25 quantify customer sales of controlled substances identified

1 as life-style drugs through a central review process.

2 Do you see that?

3 **A.** Yes.

4 **Q.** Does that fit with your knowledge that McKesson
5 immediately began modifying its policies to try to address
6 the concerns that the DEA was raising?

7 **A.** Well, according to this, yes.

8 **Q.** Let's continue on. If we go to the -- actually, if we
9 stay on the second page of the letter and go to the next
10 paragraph, it says on November 21st, 2005, DEA notified
11 McKesson through outside counsel that DEA was extremely
12 concerned. Do you see that?

13 **A.** Yes.

14 **Q.** And it identifies six specific pharmacies. Those are
15 the same pharmacies -- if you want a copy of it, I can give
16 you -- you should have it in front of you in that
17 January 23rd memo. Correct?

18 **A.** Could you repeat that, please?

19 **Q.** Yeah. It was a little funky. The DEA identified six
20 pharmacies to McKesson in its January 23rd memo; correct?

21 **A.** Yes.

22 **Q.** And in that memo -- in this letter, rather, Mr. Julian
23 is writing back and referencing those six pharmacies. Do
24 you see that?

25 **A.** Yes.

1 **Q.** He then says McKesson immediately imposed a limitation
2 on all of these pharmacies and cut sales of hydrocodone to
3 these pharmacies to only 10 percent of their prior orders.

4 Do you see that?

5 **A.** Yes.

6 **Q.** The DEA never told McKesson to put that limitation in
7 place; correct?

8 **A.** The DEA did not tell them what they should do with
9 these customers.

10 **Q.** And if we go to the next page, please, do you see at
11 the top there's a reference to the meeting we've been
12 talking about? This says January 6th. The memo says it's
13 January 3rd. But do you see that?

14 **A.** Yes.

15 **Q.** And if we look in the second to last paragraph, the
16 last full paragraph, it says, "Nevertheless, in light of
17 DEA's strong assertion at the January meeting that these
18 pharmacies are internet pharmacies, McKesson as of
19 January 9th, 2006, has terminated all sales of controlled
20 substances to all six pharmacies."

21 Did I read that correctly?

22 **A.** I'm sorry. I don't know where you are.

23 **Q.** I'm on Page 2.

24 **A.** Page 2, okay.

25 **Q.** I'm sorry, Page 3 of the letter.

1 **A.** Okay.

2 **Q.** And if you look, it's the last full paragraph right
3 there, "Nevertheless."

4 **A.** "Nevertheless," okay. Got it.

5 **Q.** And do you see where he notifies you that as of January
6 9th, 2006, these pharmacies have been terminated by
7 McKesson?

8 **A.** Okay, yes.

9 **Q.** And that's correct; right? You have no contrary
10 information, do you?

11 **A.** I don't have any contrary information.

12 MR. SCHMIDT: We move this into evidence, Your
13 Honor, Defense West Virginia 1557.

14 THE COURT: Any objection?

15 MR. IRPINO: Yes, hearsay.

16 MR. SCHMIDT: Relevant for the effect on the
17 recipient, Your Honor.

18 MR. IRPINO: That doesn't cure hearsay.

19 MR. SCHMIDT: It actually does. It's notice to
20 the witness.

21 MR. IRPINO: So you're offering it not for the
22 truth of the matter asserted as opposed to what you just
23 said.

24 MR. SCHMIDT: I think it's pretty clearly a
25 contemporaneous recording and a business record. So I'd

1 offer it for those purposes. At a minimum, it comes in for
2 notice.

3 THE COURT: Okay. I'll admit it for the limited
4 purpose stated.

5 MR. IRPINO: Did you say for the limited purpose,
6 just for notice?

7 THE COURT: For the limited purpose as stated.

8 MR. IRPINO: Okay.

9 BY MR. SCHMIDT:

10 **Q.** Now, I'm going to give you a copy, if I could, of
11 that memo. Do you remember the memo you showed the
12 Court that had blacked-out names on it? Maybe you
13 don't. Let me be more precise.

14 The January 23rd, 2006, DEA memo to you from Mr. Mapes
15 blacked out the names of the pharmacies. I don't know if
16 you recall that. Do you recall that?

17 **A.** Yes, I do.

18 **Q.** I'm going to show you one with the names.

19 **A.** Okay.

20 MR. SCHMIDT: May I approach?

21 THE COURT: Yes.

22 BY MR. SCHMIDT:

23 **Q.** And if you look at this document, you will see that
24 this is the January 23rd, 2006, memo from Michael Mapes
25 to you. Do you see that on the first page?

1 **A.** Yes.

2 **Q.** If we look at the second page, for some reason there
3 still is some blackout on the second page. But if we look
4 up at the third bullet, we can see the pharmacy names. Do
5 you see that?

6 **A.** Yes.

7 MR. SCHMIDT: We'll move this into evidence while
8 preserving our objection to this issue if we could, Your
9 Honor, just so we have something in the record with the
10 names.

11 THE COURT: Any objection?

12 MR. IRPINO: No objection, Your Honor.

13 THE COURT: It's admitted.

14 BY MR. SCHMIDT:

15 **Q.** So let's look at some of those pharmacies and let's
16 go back to that statement you said that you didn't know
17 they remained in business.

18 Do you see that one of the pharmacies is called Bi-Wise
19 Pharmacy?

20 **A.** Yes.

21 **Q.** Do you remember giving testimony about being upset
22 about these pharmacies?

23 **A.** I'm -- I don't recall the testimony.

24 **Q.** Okay. Do you know that Bi-Wise remained licensed,
25 registered by the DEA for at least nine months after

1 McKesson cut them off?

2 **A.** Okay. I didn't know that, but that's fine.

3 **Q.** Let's, let's take a look at that. Do you still have
4 that Southwood decision that you looked at in front of you?
5 It's P-23736.

6 **A.** Yes.

7 **Q.** If you want to just keep these two documents in front
8 of you -- let's put -- since it's in evidence, let's put
9 Defense West Virginia 1549 up on the board, Page 2, please.
10 And if we can cull out the Bi-Wise language so we know what
11 we're looking at.

12 Do you see the reference to Bi-Wise there?

13 **A.** Yes.

14 **Q.** All right. And then let's put up P-23736, please, Page
15 3. And if we could magnify that bottom block, please. And
16 I think I need the text above it as well. I'm sorry,
17 Mr. Reynolds.

18 If you look on the first line do you see that this is
19 talking about hydrocodone sales by this company Southwood,
20 --

21 **A.** Uh-huh.

22 **Q.** -- another distributor not in this court; correct?

23 **A.** That's correct.

24 **Q.** Southwood to Bi-Wise from January 25th after they were
25 cut off by McKesson through October, 2006. Do you see that?

1 **A.** Yes.

2 **Q.** And there's a helpful listing of month by month sales
3 that just this distributor is making to Bi-Wise; correct?

4 **A.** Okay.

5 **Q.** And you can see from looking at that, those volumes,
6 that there's over 1.2 million pills shipped to this pharmacy
7 after McKesson cut it off after it remained registered with
8 the DEA before DEA took action against Southwood; correct?

9 **A.** Okay.

10 **Q.** Let's look at -- let's go back to -- can we pull down
11 that image and look back at the memo itself.

12 Do you see that there is a pharmacy here -- let me make
13 sure I get the right one -- called Medipharma? Do you see
14 that, Medipharma?

15 **A.** Yes.

16 **Q.** And if we go to Page 2 in the Southwood opinion,
17 P-23736, and -- exactly. Thank you.

18 Do you see that there's reference to sales through
19 October, 2006 from respondent to Medipharma?

20 **A.** Yes.

21 **Q.** And can you tell from looking at those that Medipharma
22 received close to 10 million pills after McKesson cut it
23 off --

24 And, actually, the first bullet should not be
25 highlighted, but the other one should be.

1 -- 10 million pills after McKesson cut it off during
2 that nine-month period when they remained registered by the
3 DEA?

4 **A.** Yes.

5 **Q.** These pharmacies -- you talked about a concept called
6 the choke point. Do you remember that?

7 **A.** Yes.

8 **Q.** But these pharmacies, the choke point wasn't McKesson,
9 was it, because they remained open, they remained supplied;
10 correct?

11 **A.** No. McKesson supplied that Bi-Wise -- that pharmacy
12 with over 500,000, 500,000 tablets in 11 days.

13 **Q.** After McKesson cut them off, they continued to get
14 tablets and they continued to dispense; correct?

15 **A.** And there was an on-going --

16 **Q.** Is that true, sir?

17 **A.** Yeah, until the investigation was over.

18 **Q.** Correct. The only thing that shut them down, the choke
19 point in the real world was the DEA taking action in this
20 case nine months later; correct?

21 **A.** Once we got enough evidence, yes, we went after and
22 shut them down as well --

23 **Q.** Okay. And you're aware --

24 **A.** -- just like we shut down Southwood when Southwood was
25 distributing to them as well.

1 Q. And you're aware that this happened with every one of
2 the pharmacies listed in the McKesson memo, Defense West
3 Virginia 1549; correct?

4 A. Well, I don't know because the memo we have was blacked
5 out so --

6 Q. I've given you the un-blackened one.

7 A. Now I have the un-blackened one.

8 Q. Now you know; right?

9 A. Yeah, but it doesn't matter because they dispensed
10 500,000 dosage units in 11 days. I defy you to see a
11 pharmacy that dispenses that much in 11 days.

12 Q. Sir, did you cut them off immediately after that?

13 A. I couldn't because of due process. Obviously, you know
14 about due process. Due process means that I have to do my
15 investigation in line to ensure that it's done appropriately
16 and I have enough evidence to shut them down.

17 MR. SCHMIDT: Your Honor, I think the witness is
18 pretty clearly arguing with me. I'd ask him just to answer
19 the questions.

20 THE COURT: He can explain his answer. Go ahead
21 and ask him the next question.

22 MR. SCHMIDT: My reaction was just to, you know,
23 the due process. I recognize I'm dealing with a lawyer as a
24 witness, but I'm trying to keep it polite.

25 BY MR. SCHMIDT:

1 Q. You can't point me to a single pharmacy you know of
2 that has ever gone out of business because a single
3 distributor cut them off; correct?

4 A. I can't -- I mean, do you know how many pharmacies have
5 been cut off? I have no idea.

6 Q. You can't point me to pharmacies that have been cut off
7 because the DEA takes away their registration. True?

8 A. And it takes time, as I've said. You just don't take
9 away a registration. It takes time.

10 Q. Can you answer my question now, sir?

11 A. Yes.

12 Q. Thank you. Now, you, you in your testimony talked
13 about whether there was a systemic issue at this point in
14 time with McKesson. Do you remember that testimony?

15 A. Yes.

16 Q. Do you know what the name of McKesson's suspicious
17 Order Monitoring Program was at this time?

18 A. I believe it was, it was Section 55 I think.

19 Q. Section 55 in the operations manual?

20 A. Yes.

21 Q. Okay. You never went on-site, though, in your career
22 and reviewed a Suspicious Order Monitoring System; correct?

23 A. No, I did not.

24 Q. So that testimony that you gave about inspections just
25 a little while ago, that comes without you actually having

1 inspected yourself a Suspicious Order Monitoring System
2 on-site at a company; correct?

3 **A.** I don't believe back then I did inspections on -- I was
4 doing audits when I did -- when I went out on-site.

5 **Q.** Sir, let me try one more time. Is it true that you
6 have never gone on-site and reviewed a Suspicious Order
7 Monitoring System?

8 **A.** That's correct. I did not do a Suspicious Order
9 Monitoring System, no.

10 **Q.** Did you know that McKesson implemented its policy at
11 the distribution center level, Section 55 that we're
12 discussing?

13 **A.** Okay.

14 **Q.** Did you know that?

15 **A.** Did I know that -- yeah, yes. It's a centralized
16 system. But the system is centralized, but it operates out
17 of the facilities, but that doesn't mean it's not a
18 centralized system.

19 **Q.** So let's go back to that memo. Do you still have that
20 memo --

21 **A.** Which one?

22 **Q.** -- in front of you? Defense West Virginia 1549, the
23 January 23rd, 2006 DEA memo.

24 **A.** Yes.

25 **Q.** Do you see that?

1 **A.** Yes.

2 **Q.** I want you to -- I want to just walk through a few
3 details in this memo, please.

4 Do you remember saying on direct examination that it
5 takes three to five months, sometimes longer, to use ARCOS
6 data?

7 **A.** Yes.

8 **Q.** What's the date of the meeting that this memo
9 summarizes?

10 **A.** January 23rd.

11 **Q.** And what is the date of the period of sales that it
12 discusses on Page 2 in the third bullet?

13 **A.** October 10th through October 21st, 2005.

14 **Q.** Is that more or less than the three to five months you
15 told us about?

16 **A.** Well, they didn't pull them on October 10th, 2005. If
17 I remember correctly, it's going back, but I seem to
18 remember those were pulled in December.

19 **Q.** Was it more or less than the three to five months you
20 told us about, sir?

21 **A.** Again, it's a little less than the three months.

22 **Q.** If we go back into December, is from October 21st to
23 December more or less than the three to five months,
24 sometimes longer, that you told us about?

25 **A.** It's, it's less. But if you notice, that's why we did

1 a 10-day or 11-day period because that information was
2 already validated.

3 **Q.** I'm just finding a document. While I'm looking for it
4 do you have P-1207? Let me make sure I have the number
5 right. Yeah, P-1207.

6 Why don't I come back to this document in a moment,
7 sir.

8 Actually, do you still have in front of you P-1207?
9 It's a statement from June 24th, 2008, to the House of
10 Representatives.

11 **A.** Okay, got it.

12 **Q.** Look with me, if you would, at Page 7 of this document
13 while we're on the subject of ARCOS data, please.

14 **A.** Yes.

15 **Q.** And do you see that there's a legislative response --
16 And why don't we put this up on the screen, please?

17 **A.** Sure.

18 **Q.** P-1207, Page 8 of the numbering in the bottom right.

19 Do you see in the bottom half it says "DEA's response"?
20 Do you see that, Mr. Rannazzisi?

21 **A.** Yes.

22 **Q.** You talked about challenges. Do you see up above those
23 challenges, the challenges of internet pharmacies?

24 **A.** Yes.

25 **Q.** Despite these internet pharmacy challenges, DEA has

1 been successfully using the tools that we have to counter
2 this growing threat. We are using all current regulatory
3 tools possible to identify and shut down those that choose
4 to operate outside of the Controlled Substances Act.

5 Do you see that?

6 **A.** Yes.

7 **Q.** And then it says, "DEA is using the --" and it gives
8 the full name but I'm going to use ARCOS, "to identify high
9 or excessive volume purchases and determine which retail
10 pharmacies and practitioners are likely to be involved in
11 the illicit distribution of controlled substances via the
12 internet."

13 Do you see that statement you made to Congress?

14 **A.** Yes.

15 **Q.** Was that true?

16 **A.** Yes.

17 **Q.** Were you able to use ARCOS to identify high or
18 excessive volume purchases and determine which retail
19 pharmacies and practitioners are likely to be involved in
20 the illicit distribution of controlled substances via the
21 internet?

22 **A.** Yes, retrospectively we can.

23 **Q.** And you were able to do that successfully, correct, as
24 you say in your first line?

25 **A.** Yes.

1 **Q.** And then if we go down, you say, "Both manufacturers
2 and distributors are only required to provide information
3 electronically to the ARCOS database about any sale of
4 narcotic substances. Although this data is limited to
5 narcotics, DEA is able to develop leads and augment
6 investigations from this information."

7 Was that truthful that you could develop leads and
8 augment investigations with ARCOS data?

9 **A.** Yes.

10 **Q.** And there's no reference in here to ARCOS data being --
11 requiring three to five months, sometimes longer, to be
12 validated; correct?

13 **A.** No. It's -- I've already said that.

14 **Q.** Thank you.

15 **A.** Our analysis using ARCOS is always retrospective and
16 it's always behind. That's, that's just the way it is. We
17 don't have the ability to look at real-time data unless
18 you're supplying a suspicious order.

19 **Q.** Nothing you just said appears in this statement to
20 Congress, does it?

21 **A.** No, that doesn't appear.

22 **Q.** Let's go back to the memo, please, the January 23rd,
23 2006 memo, Defense West Virginia 1549.

24 And when you're caught up with me, I'm going to go to
25 the second page, please, sir.

1 **A.** Okay.

2 **Q.** In the third paragraph from the bottom it says,
3 "Through the course of the above discussions, McKesson
4 Corporation by their own admission was unable to provide a
5 plausible explanation for the sales."

6 Do you see that?

7 **A.** Yes.

8 **Q.** And you understand that that's DEA characterizing
9 McKesson's response; correct?

10 **A.** Yes.

11 **Q.** Now, you told us a story that you looked at someone at
12 McKesson and they smiled and they said, "You got us."

13 **A.** Yes.

14 **Q.** Who was that?

15 **A.** Whoever was there. I don't know the gentleman who was
16 there. That was a long time ago. But, yes, that's --

17 **Q.** I think there were three or four gentlemen there.
18 Which one of them said it? It's on the front page of the
19 memo if you need to look at it.

20 **A.** I don't recall which one to be honest with you. But I
21 do recall right after that was when I asked them for the
22 voluntary surrender of their registration.

23 **Q.** This memo doesn't document someone from McKesson
24 saying, "You got us," and smiling, does it?

25 **A.** I don't think the memo that we put that in there.

1 Q. Let's go back to the first page, please. And if we
2 look at the second and third paragraphs on the first page,
3 do you see it talks about representatives of McKesson?

4 A. Yes.

5 Q. And do you see it talks about representatives of the
6 Drug Enforcement Administration?

7 A. Yes.

8 Q. And for McKesson let's highlight Donald Walker, Bill
9 Mahoney, Gary Hilliard, please. Do you see those names? Do
10 you remember meeting those gentlemen?

11 A. Like I said, it was a meeting. I remember the person
12 having that little smile and saying, "I guess you got us."
13 I can't explain it.

14 Q. Which one is that?

15 A. I don't remember.

16 Q. Okay. Michael Mapes from the DEA, do you see that?

17 A. Yes.

18 Q. Kyle Wright from the DEA?

19 A. Yes.

20 Q. Are you aware that everyone that's been highlighted has
21 been deposed and not one of them has told that story about a
22 smile and, "You got us"?

23 A. Well, I'm telling you it happened. And that's when I
24 asked them for their voluntary surrender.

25 Q. Can you answer my question now, sir?

1 **A.** Yes.

2 **Q.** Are you aware that every one of those people who have
3 been highlighted have been deposed and not one of them has
4 told that story?

5 **A.** Okay.

6 **Q.** Are you aware of that?

7 **A.** No, I'm not aware of that.

8 **Q.** Are you aware that Michael Mapes, the DEA agent,
9 testified under oath that, quote, if McKesson had said, hey,
10 we're doing this or we're selling with blinders on and we're
11 not looking or we haven't been following this stuff or we
12 haven't been checking the diversion the way the law says, if
13 they told you that at the meeting, you surely would have
14 noted it, wouldn't you? Did you know he agreed with that
15 statement in sworn testimony?

16 MR. IRPINO: Your Honor, we're now reading
17 deposition testimony from a witness outside of this court.
18 It's actually hearsay beyond hearsay.

19 THE COURT: He's cross -- this is proper
20 cross-examination. Overruled.

21 Go ahead, Mr. Schmidt.

22 BY MR. SCHMIDT:

23 **Q.** Are you aware that -- you've looked at Mr. Mapes's
24 testimony; correct?

25 **A.** No, I don't believe I have.

1 **Q.** Okay. Did you know he gave that testimony, that if
2 that kind of statement was made to him, he would have noted
3 it in that memo?

4 **A.** I, I don't know what Mr. Mapes would or wouldn't do.

5 **Q.** Let's go back to the second page, if we could. I want
6 to ask you a few questions about this language down at the
7 bottom, please, sir.

8 And this is -- this paragraph at the bottom references
9 this point you made that during the meeting, Mr. Hilliard --
10 or at the conclusion of the meeting, Mr. Hilliard said we
11 weren't picking up the hydrocodone generics in the run of
12 our data that we were doing. Do you remember giving
13 testimony about that?

14 **A.** Yes.

15 **Q.** Are you aware that he's testified, Mr. Hilliard, that
16 that was an acute issue as opposed to a chronic issue?

17 **A.** I'm not aware of that, but it still allowed 500,000, or
18 two million dosage units to go downstream.

19 **Q.** Do you have any contrary information indicating that
20 this was a chronic issue outside of this report at this
21 distribution center?

22 **A.** No.

23 **Q.** And are you aware that McKesson after immediately fixed
24 that reporting issue after they realized it at this
25 distribution center at this point in time?

1 **A.** Well, I would hope so.

2 **Q.** Did you check to make sure they did as part of your
3 work?

4 **A.** I'm sure the staff did, yes.

5 **Q.** All right. And to be clear, this was 16 years ago;
6 correct?

7 **A.** Yes. It was a long time ago.

8 **Q.** And McKesson changed its Suspicious Order Monitoring
9 Programs as a result of these discussions; correct?

10 **A.** Yes.

11 **Q.** And, in fact, you know McKesson has gone through
12 several iterations of its Suspicious Order Monitoring
13 Programs trying to change them as diversion and DEA guidance
14 changes over time; correct?

15 **A.** Am I talking about back then or now? I mean --

16 **Q.** Up through your tenure. Are you aware --

17 **A.** Through my tenure I know they changed their system,
18 yes.

19 **Q.** Okay. I'd like to go back to P-16 which was that Order
20 to Show Cause document. Let me know when you've got it in
21 front of you, sir.

22 **A.** I'm not sure which one it is.

23 **Q.** If it helps, it's a pretty thick packet and I can put
24 what I'm going to show you up on the screen too.

25 **A.** Okay.

1 Q. What I'd like to do, in the interest of time, I'll just
2 go straight there, is -- let's go to Page 42 of the
3 document, please.

4 Do you remember not 15 minutes ago telling me about due
5 process?

6 A. Yes.

7 Q. What due process is is both sides in a contested matter
8 get to have their say; right?

9 A. Yes.

10 Q. And you understand that when you issued your Order to
11 Show Cause McKesson stated their position starting on Page
12 42 of this document?

13 A. Yes.

14 Q. You know they had facts that they thought were
15 important; right? I think you nodded, but she's got to have
16 an oral answer.

17 A. Yes.

18 Q. Thank you.

19 MS. SINGER: Objection. The witness can't testify
20 to McKesson's state of mind.

21 MR. SCHMIDT: I don't think that's what I asked,
22 Your Honor.

23 THE COURT: No, overruled. I don't think that was
24 the question.

25 BY MR. SCHMIDT:

1 Q. Let's go to Page 43, please.

2 A. I'm at 43.

3 Q. If you look at the bottom there's Mr. Mahoney who we
4 saw in the memo. And if we go to Page 44, do you see
5 there's nine different witnesses listed in total?

6 A. Yes.

7 Q. And let's continue on to Page 45. It starts "proposed
8 testimony of Mr. Mahoney." Do you see that?

9 A. Yes.

10 Q. And let's go to page -- in the interest of time, I'm
11 just going to go through some quick points on this. Can we
12 go to Page 48, please?

13 A. Yes.

14 Q. Do you see where it says "Verification of customers"
15 and it talks about steps McKesson takes to verify its
16 customers?

17 A. Yes.

18 Q. Have you personally reviewed the details of everything
19 McKesson was doing at this point in time to verify
20 customers?

21 A. Based on this document or based on when I was at DEA?

22 Q. Yeah. Did you do that? Did you personally look at how
23 McKesson -- all the details of how it verified its customers
24 at this point in time?

25 A. When I was at DEA?

1 Q. Yes.

2 A. The staff would do that.

3 Q. Did you do it? That's my question, sir.

4 A. If I was preparing for -- I don't recall if I did it or
5 not. Depends on if I was preparing for testimony or not.

6 Q. Do you recall any details about how McKesson verified
7 its customers at this point in time that you personally
8 reviewed?

9 A. I don't recall.

10 Q. Okay. Let's go to the next page. Do you see that
11 there's a reference about four lines down to the reports
12 that McKesson would generate? "He will discuss the reports
13 generated." Do you see that?

14 A. Four lines down on what page?

15 Q. 49, sir.

16 A. Okay. "He will discuss --" yes.

17 Q. Do you see there's a reference to daily reports that
18 went to the DEA?

19 A. Okay.

20 Q. Were you aware that McKesson was providing daily
21 reports to the DEA from its distribution centers?

22 A. Back then?

23 Q. Yes.

24 A. I don't remember daily. I remember -- I don't remember
25 the daily reports, no.

1 **Q.** Okay. Let's go to Page 50, please. In the first full
2 paragraph it states, "He will discuss procedures that
3 Lakeland DC uses to follow up on customers, with customers
4 on potential suspicious orders."

5 Do you see that?

6 **A.** Yes.

7 **Q.** Do you know right now whether you personally reviewed
8 all the details and the procedures that this distribution
9 center or any other distribution center at McKesson at this
10 point in time used to follow up with customers on potential
11 suspicious orders?

12 **A.** I'm sorry. You're going to have to repeat that
13 question.

14 **Q.** Sure. Do you know -- can you tell us now whether you,
15 in fact, looked at all of the details regarding the
16 procedures that McKesson distribution centers used to follow
17 up with customers on potential suspicious orders at this
18 point in time?

19 **A.** No, I didn't -- I was briefed -- as I said previously,
20 I was briefed on their procedures prior to the issuance of
21 the orders.

22 **Q.** Just if we go back to Page 49. Do you remember saying
23 you don't -- you didn't recall the daily reports? Do you
24 remember that?

25 **A.** Yes.

1 Q. You don't have any information that they were not sent,
2 do you?

3 A. I don't have any information they were not sent. I
4 don't remember being briefed on daily reports, though.

5 Q. Sometimes you hear it, sometimes you don't. That's why
6 it's called brief. Right?

7 A. No. I took those briefings pretty seriously. I
8 listened to everything.

9 Q. I'm not suggesting you didn't listen, sir.

10 A. Okay.

11 Q. Do you understand "brief" means a summary of what's
12 important; correct?

13 A. I understand that, but the word "brief" doesn't really
14 capture these briefings. A brief briefing could be two,
15 three hours. So that's not really brief.

16 Q. Let's look at Page 51, please.

17 Do you see it talks about how in the bottom carry-over
18 paragraph Mr. Mahoney will testify as to the due diligence
19 completed for each of the seven pharmacies identified in
20 DEA's Order to Show Cause. Do you see that?

21 A. I'm sorry. Which paragraph are you on?

22 Q. Bottom paragraph, Page 51. It's also up on the screen
23 if you need it.

24 A. Okay.

25 Q. Do you see that?

1 **A.** Yes.

2 **Q.** And did you personally review the full due diligence
3 McKesson completed for each of those pharmacies?

4 **A.** No, I did not review those due diligence.

5 **Q.** Let's look at Page 59, please. Do you see that there's
6 proposed testimony from Gary Hilliard?

7 **A.** Yes.

8 **Q.** Do you know if you've ever met Mr. Hilliard?

9 **A.** I'm sure I did.

10 **Q.** Okay. You couldn't pick him out I take it?

11 **A.** From 16 years ago?

12 **Q.** Yeah.

13 **A.** Probably not.

14 **Q.** Okay. Let's look at his testimony, his proposed
15 testimony on Page 61. Do you see there's a heading that
16 says "Suspicious Orders"?

17 **A.** Got it.

18 **Q.** Under that heading it says, "Mr. Hilliard will testify
19 as to McKesson's participation in the DEA Suspicious Orders
20 Task Force."

21 Do you see that?

22 **A.** Yes.

23 **Q.** "He will testify that the Suspicious Order Task Force
24 was created in cooperation with DEA in the mid to late
25 1990s."

1 Do you see that?

2 **A.** Yes.

3 **Q.** Were you part of that DEA Suspicious Orders Task Force?

4 **A.** No. That Suspicious Orders Task Force, though, was for
5 chemicals, not for controlled substances.

6 **Q.** Did you attend meetings of that Suspicious Order Task
7 Force?

8 **A.** No, but I received reports on the Suspicious Orders
9 Task Force because I was the clandestine lab coordinator for
10 the Detroit field division at the time.

11 **Q.** Do you see where he says five lines down, "Mr. Hilliard
12 will testify that the industry and DEA agreed on a variation
13 factor to allow for seasonal fluctuations." But then he
14 says, "The threshold criteria established for suspicious
15 orders involved a factor of three times the average for
16 CII --"

17 Do you recognize that as Schedule II controlled
18 substances?

19 **A.** Yes.

20 **Q.** And a factor of eight times average for III to V.

21 Do you recognize that as Schedule III to V controlled
22 substances?

23 **A.** Yes.

24 **Q.** And List I products. Do you see that?

25 **A.** Yes.

1 Q. Were you at any of those meetings, sir?

2 A. No, I was not.

3 Q. Let's go to Page 71, and then we'll be done with this
4 document.

5 Do you see that there's reference to testimony from
6 Donald Walker at McKesson?

7 A. Yes.

8 Q. If we flip over to Page 72, do you see on Page 72 there
9 is reference to educational information that McKesson has
10 provided to its employees and operations and sales regarding
11 internet pharmacies?

12 A. I'm sorry. Where are we? I'm on Page 72.

13 Q. Very bottom paragraph. It's up on the screen as well
14 if that helps.

15 A. Yes.

16 Q. Do you see that?

17 A. Yes.

18 Q. Am I correct that you've not reviewed those materials
19 in any detail?

20 A. No, I have not.

21 MR. SCHMIDT: Your Honor, I can do a new topic but
22 I think I'm out of time.

23 THE COURT: Is this a good place to stop?

24 MR. SCHMIDT: This is a great place to stop.

25 THE COURT: Okay.

1 Mr. Rannazzisi, we'll have to have you back here at
2 9:00 in the morning, sir.

3 THE WITNESS: Thank you very much.

4 THE COURT: Okay. We'll be in recess until 9:00.

5 MR. SCHMIDT: Thank you, Your Honor.

6 (Trial recessed at 5:01 p.m.)
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1 CERTIFICATION:

2 I, Ayme A. Cochran, Official Court
3 Reporter, and I, Lisa A. Cook, Official Court Reporter,
4 certify that the foregoing is a correct transcript from
5 the record of proceedings in the matter of The City of
6 Huntington, et al., Plaintiffs vs. AmerisourceBergen
7 Drug Corporation, et al., Defendants, Civil Action No.
8 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as
9 reported on June 8, 2021.

10
11 S\Ayme A. Cochran

12 Reporter

13 s\Lisa A. Cook

14 Reporter

15 —

16 June 8, 202117 Date
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\$	123:19, 129:21, 130:18, 131:10, 133:19	2000s [1] - 215:6	21st [4] - 16:7, 221:10, 232:13, 232:22	32502 [1] - 2:14
\$180,000 [1] - 208:12	15 [6] - 25:14, 25:23, 96:6, 123:19, 191:13, 241:4	2004 [2] - 214:23, 215:2	22 [2] - 1:16, 213:5	33 [3] - 151:20, 187:3, 202:22
\$860,000 [1] - 208:8	15,000 [1] - 185:8	2005 [22] - 7:23, 9:9, 16:7, 36:21, 60:16, 60:18, 66:14, 105:14, 109:18, 114:20, 146:2, 204:18, 212:1, 212:8, 212:17, 212:18, 212:20, 213:21, 214:20, 221:10, 232:13, 232:16	2216 [1] - 3:7	34 [2] - 79:17, 80:1
'	15-milligram [1] - 25:11	2006 [21] - 9:24, 19:14, 20:7, 31:24, 35:20, 36:13, 36:15, 36:21, 191:11, 204:19, 204:20, 219:5, 220:5, 222:19, 223:6, 224:14, 227:19, 231:23, 235:23	226 [2] - 171:25, 172:1	35 [1] - 80:14
'05 [1] - 53:12	1549 [4] - 226:9, 229:3, 231:22, 235:23	2006-2007 [1] - 215:24	229 [2] - 213:5, 213:11	350 [1] - 210:24
'06 [1] - 53:12	1557 [2] - 220:4, 223:13	2007 [14] - 48:13, 48:19, 59:17, 63:3, 68:20, 69:9, 77:18, 78:5, 142:21, 142:23, 143:23, 146:4, 149:19, 215:9	2291 [1] - 154:4	37 [1] - 98:1
'80s [3] - 213:2, 214:21	15910 [1] - 3:18	2008 [9] - 74:2, 74:22, 76:20, 78:14, 80:22, 81:11, 95:17, 215:12, 233:9	22nd [3] - 68:20, 69:9, 122:12	3843 [1] - 5:14
'96 [1] - 55:25	16 [3] - 133:19, 240:5, 246:11	2010 [2] - 84:3, 84:4	23 [1] - 151:12	39 [1] - 122:14
0	16,000 [1] - 185:9	2011 [5] - 84:23, 84:25, 87:1, 97:6, 98:25	23rd [9] - 219:5, 219:19, 221:17, 221:20, 224:14, 224:24, 231:23, 232:10, 235:22	3:17-cv-01362 [2] - 1:5, 250:8
00907 [2] - 2:5, 2:17	1600 [1] - 3:17	2012 [7] - 75:25, 96:2, 96:3, 96:13, 97:6, 189:4, 206:2	24th [1] - 233:9	3:17-cv-01665 [2] - 1:11, 250:8
1	16th [2] - 139:19, 212:14	2013 [1] - 192:18	25 [1] - 5:5	3:30 [2] - 176:8, 184:6
1 [6] - 47:4, 47:25, 48:6, 73:25, 75:4, 76:19	17 [2] - 213:5, 213:12	2014 [1] - 202:13	252,100 [1] - 16:14	3:31 [1] - 184:9
1,000 [1] - 211:4	1717 [2] - 6:6, 6:13	2015 [2] - 166:11, 212:1	25301 [3] - 2:8, 3:13, 4:19	3rd [9] - 9:23, 13:22, 14:9, 31:22, 36:15, 192:18, 219:19, 222:13
1.2 [1] - 227:6	18.9 [1] - 123:1	2017 [3] - 202:13, 208:7	25322 [1] - 6:9	4
1.3-1.4 [1] - 171:12	18th [2] - 138:2, 220:5	2019 [2] - 213:4, 213:9	25338-3843 [1] - 5:15	4 [5] - 32:19, 33:2, 48:15, 48:22, 145:3
10 [5] - 139:5, 211:23, 222:3, 227:22, 228:1	19 [4] - 130:17, 131:12, 131:13, 133:20	202 [2] - 2:4, 2:16	25701 [1] - 3:10	40 [1] - 23:22
10,000 [1] - 185:8	19087 [1] - 6:15	2020 [1] - 212:14	25th [1] - 226:24	401 [2] - 2:10, 4:6
10-day [1] - 233:1	19103 [2] - 6:6, 6:13	2021 [4] - 1:19, 7:4, 250:9, 250:15	26 [1] - 45:3	405 [1] - 2:7
10-milligram [3] - 16:18, 25:11, 25:14	1970 [1] - 171:20	208873 [1] - 96:6	26.2 [1] - 123:3	42 [3] - 122:14, 241:2, 241:12
100 [2] - 191:6, 200:12	1988 [2] - 214:23, 215:2	20th [1] - 86:12	26th [1] - 213:4	43 [2] - 242:1, 242:2
1001 [2] - 2:10, 4:6	1990s [1] - 246:25	21 [9] - 48:18, 49:3, 69:16, 81:10, 89:22, 122:11, 141:4, 172:2, 196:20	27 [3] - 45:3, 85:24, 142:21	44 [1] - 242:4
1022 [1] - 3:5	1996 [1] - 139:19	219 [1] - 95:9	27th [2] - 116:18, 144:13	440 [1] - 188:15
10:30 [1] - 36:5	1998 [1] - 53:23		28 [3] - 3:15, 4:3, 4:9	45 [2] - 122:21, 242:7
10:34 [1] - 67:25	19th [1] - 59:17		29 [2] - 204:22, 205:4	46 [1] - 81:1
10th [6] - 16:7, 60:16, 60:18, 60:23, 232:13, 232:16	1:00 [1] - 122:22		29464 [3] - 3:15, 4:4, 4:9	48 [1] - 242:12
11 [7] - 16:24, 17:18, 17:24, 140:2, 228:12, 229:10, 229:11	1:45 [2] - 122:5		2:00 [2] - 122:4, 122:23	49 [3] - 73:2, 243:15, 244:22
11-day [3] - 16:9, 16:14, 233:1	1st [1] - 36:21		2d [1] - 188:15	4th [3] - 9:24, 35:18, 36:13
11:53 [1] - 122:6	2		2nd [1] - 192:18	5
120 [4] - 18:3, 191:6, 194:2, 194:4	2 [11] - 15:24, 36:17, 47:14, 48:1, 68:21, 154:22, 222:23, 222:24, 226:9, 227:16, 232:12		3	5 [5] - 36:17, 60:10, 89:12, 90:16, 190:7
126 [1] - 3:5	20 [10] - 45:3, 45:7, 122:11, 200:20, 200:22, 201:16, 201:17, 201:19, 203:4		3 [11] - 60:10, 60:12, 68:22, 80:14, 144:13, 145:3, 145:8, 172:1, 222:25, 226:15	5-milligram [1] - 16:17
1260 [2] - 73:25, 75:3	20,000-foot [1] - 196:16		30 [6] - 23:22, 24:17, 25:23, 80:22, 81:11, 123:9	5.2 [1] - 60:21
13 [2] - 151:11, 156:6	20-some [1] - 123:8		30(b)(6) [1] - 55:24	50 [2] - 45:7, 244:1
1300 [1] - 6:15	20001 [1] - 5:12		30-milligram [2] - 24:17, 25:11	500 [1] - 18:2
1301.7(4)(b) [1] - 48:18	20004 [1] - 4:7		300 [1] - 210:22	500,000 [4] - 228:12, 229:10, 239:17
1301.74(b) [3] - 64:16, 81:10, 172:13	20005 [3] - 4:14, 4:16, 5:5		30s [1] - 25:15	51 [2] - 245:16, 245:22
1301.74(b) [3] - 49:4, 69:17, 89:22			30th [1] - 78:14	5126 [2] - 140:3, 140:15
130174 [1] - 172:2			3100 [2] - 6:5, 6:12	5195 [1] - 95:9
1311 [2] - 2:4, 2:16			316 [1] - 2:13	520,000 [1] - 17:24
14 [6] - 123:13,			31st [3] - 36:21, 48:13, 48:18	54 [2] - 77:7, 122:15

56th ^[1] - 3:5 57.8 ^[1] - 122:15 57/42 ^[1] - 125:3 59 ^[3] - 92:22, 246:5 5:01 ^[1] - 249:6 5th ^[1] - 77:18	197:9, 197:11, 198:2, 198:24, 201:5, 201:12 850 ^[1] - 5:12 8873 ^[1] - 87:1	90:1, 90:14 ACKERMAN ^[10] - 2:9, 33:23, 34:1, 75:5, 75:11, 214:3, 214:5, 214:8, 214:14, 219:14 Ackerman ^[7] - 33:18, 33:19, 34:19, 54:8, 75:12, 127:7, 136:5 Ackerman's ^[1] - 34:16 acknowledge ^[1] - 125:23 acknowledged ^[3] - 50:21, 53:10, 53:17 acquire ^[1] - 191:3 acquired ^[1] - 164:3 acquiring ^[1] - 36:22 Act ^[15] - 60:8, 62:14, 62:23, 72:15, 115:22, 116:4, 116:25, 121:16, 144:10, 154:21, 171:14, 171:19, 203:14, 204:7, 234:4 act ^[7] - 37:10, 117:13, 145:18, 155:22, 172:5, 172:7, 201:8 acting ^[2] - 186:6, 204:18 action ^[19] - 28:21, 39:20, 40:25, 43:21, 72:12, 72:16, 74:2, 74:17, 74:22, 75:25, 76:21, 92:1, 113:1, 141:14, 185:17, 186:1, 207:13, 227:8, 228:19 Action ^[4] - 1:4, 1:10, 250:7, 250:8 actions ^[10] - 72:6, 72:9, 74:20, 75:25, 78:16, 115:14, 150:5, 158:6, 170:11, 181:19 activities ^[6] - 35:2, 83:24, 139:15, 154:1, 188:10, 196:3 activity ^[4] - 23:13, 119:22, 141:6, 141:7 actual ^[1] - 135:23 acute ^[1] - 239:16 acutely ^[1] - 136:3 add ^[8] - 19:2, 42:14, 46:18, 56:17, 56:24, 137:2, 137:4, 194:21 add-on ^[1] - 46:18 added ^[2] - 134:14, 137:8 addiction ^[1] - 207:24	addition ^[11] - 23:17, 66:17, 88:14, 89:23, 118:5, 118:16, 133:12, 173:15, 181:22, 201:14, 207:17 additional ^[4] - 15:11, 72:6, 72:9, 86:16 address ^[9] - 22:17, 23:9, 33:23, 38:18, 75:6, 121:10, 169:24, 170:11, 221:5 addressed ^[2] - 31:12, 73:22 adequate ^[3] - 48:11, 69:8, 80:20 adjust ^[1] - 199:9 administration ^[6] - 187:17, 187:18, 187:21, 189:9, 189:13, 191:16 Administration ^[3] - 68:14, 220:10, 237:6 Administrative ^[1] - 96:11 administrative ^[9] - 28:20, 29:9, 31:16, 32:8, 41:12, 89:24, 147:23, 150:2, 218:12 administrator ^[10] - 61:15, 78:18, 78:19, 81:22, 89:6, 89:10, 198:17, 198:20, 198:21, 198:22 Administrator ^[27] - 29:21, 29:23, 30:10, 30:19, 30:23, 31:6, 32:11, 57:15, 59:21, 61:17, 72:8, 102:15, 148:23, 149:6, 156:17, 160:4, 162:21, 180:21, 181:20, 183:13, 186:25, 195:10, 198:6, 204:17, 205:7 admissibility ^[2] - 11:23, 88:25 admissible ^[1] - 188:18 admission ^[4] - 83:5, 88:12, 95:3, 236:4 admit ^[15] - 11:11, 33:1, 33:12, 35:13, 86:21, 87:12, 150:12, 150:25, 151:1, 154:3, 155:8, 155:13, 188:1, 189:18, 224:3	admitted ^[16] - 35:14, 44:24, 73:1, 86:23, 87:1, 87:5, 87:14, 88:12, 116:10, 116:12, 150:16, 154:5, 154:9, 188:20, 189:23, 225:13 adults ^[1] - 190:21 advance ^[2] - 93:2, 94:10 adversarial ^[1] - 205:21 adverse ^[2] - 135:19, 135:24 advise ^[1] - 150:4 advised ^[1] - 52:21 advisement ^[1] - 132:8 advocacy ^[1] - 97:16 afoot ^[1] - 31:11 afoul ^[1] - 170:21 afternoon ^[4] - 136:6, 184:13, 209:24, 210:2 afternoons ^[3] - 123:10, 125:12, 135:9 agency ^[5] - 31:16, 93:24, 193:11, 193:12, 210:5 agent ^[1] - 238:8 agents ^[1] - 211:14 aggregate ^[1] - 198:17 aggregator ^[2] - 163:13, 165:4 ago ^[10] - 34:6, 90:15, 132:3, 159:18, 230:25, 236:16, 240:5, 240:7, 241:4, 246:11 agree ^[3] - 54:5, 135:12, 208:13 agreed ^[4] - 96:20, 134:12, 238:14, 247:12 Agreement ^[26] - 44:11, 44:15, 44:23, 45:25, 51:3, 57:24, 58:6, 58:7, 58:19, 68:11, 69:22, 70:2, 71:9, 79:14, 80:4, 80:5, 80:7, 80:12, 81:3, 83:13, 83:22, 96:3, 96:11, 96:12, 96:16, 96:19 agreement ^[14] - 48:7, 49:6, 50:11, 61:20, 68:15, 68:19, 68:21, 69:16, 69:19, 70:9,
6	9			
6 ^[7] - 32:13, 32:15, 32:19, 33:2, 48:20, 57:25, 190:6 60 ^[3] - 208:14, 208:19, 209:8 600 ^[1] - 2:13 61 ^[2] - 77:19, 246:15 65,000 ^[1] - 171:10 66 ^[1] - 211:18 67 ^[1] - 78:6 6th ^[2] - 3:5, 222:12	9 ^[1] - 155:15 901 ^[1] - 4:18 91436 ^[1] - 3:18 93 ^[1] - 122:13 99 ^[1] - 184:24 9:00 ^[3] - 7:4, 249:2, 249:4 9th ^[3] - 2:10, 222:19, 223:6			
7	A			
7 ^[5] - 120:9, 120:10, 233:12 7-and-a-half- milligram ^[1] - 16:17 7.3 ^[1] - 123:2 70130 ^[1] - 3:8 707 ^[1] - 4:18 71 ^[1] - 248:3 716 ^[1] - 3:12 72 ^[3] - 248:8, 248:12 722 ^[1] - 188:15 725 ^[2] - 4:13, 4:15 73 ^[3] - 92:16, 92:17, 92:20 74(b) ^[1] - 172:9 745 ^[3] - 192:24, 193:20, 193:24 7th ^[4] - 78:5, 142:23, 143:23, 144:13	a.m ^[3] - 7:5, 67:25, 122:6 abatement ^[1] - 204:9 ABDC ^[3] - 51:14, 212:12, 212:16 ability ^[5] - 112:9, 124:25, 168:10, 204:25, 235:17 able ^[6] - 53:13, 169:19, 171:4, 234:17, 234:23, 235:5 absent ^[1] - 166:24 Absolutely ^[2] - 93:12, 199:4 absolutely ^[6] - 12:1, 16:24, 35:23, 83:18, 106:17, 113:23 abuse ^[2] - 117:18, 117:19 accept ^[1] - 52:5 access ^[11] - 159:13, 160:16, 161:21, 162:22, 163:10, 163:23, 166:15, 167:13, 168:18, 168:20, 169:14 accomplish ^[1] - 31:7 accordance ^[1] - 49:3 according ^[1] - 221:7 Accordingly ^[1] - 117:21 account ^[4] - 12:18, 123:11, 198:23, 199:1 accountability ^[1] - 179:18 accurate ^[2] - 61:23, 159:7 accurately ^[3] - 11:8,			
8				
8 ^[6] - 1:19, 7:4, 81:7, 233:18, 250:9, 250:15 801 ^[1] - 3:10 803 ^[1] - 188:19 803(8)(A)(i) ^[1] - 188:8 803(8)(A)(iii) ^[1] - 188:11 8038(a)(1) ^[1] - 34:25 80s ^[1] - 156:16 823 ^[1] - 141:4 823(e) ^[2] - 118:23, 119:6 824 ^[1] - 141:4 826 ^[7] - 196:20,				

<p>80:17, 81:8, 89:25, 96:22</p> <p>agreements [5] - 157:7, 157:9, 157:10, 157:11, 182:25</p> <p>Agreements [7] - 82:9, 82:14, 82:20, 82:25, 83:8, 83:25, 216:3</p> <p>agrees [3] - 48:24, 50:5, 98:14</p> <p>ahead [33] - 19:10, 26:20, 27:15, 33:25, 34:23, 36:9, 38:10, 38:12, 43:14, 46:25, 50:6, 52:9, 53:4, 71:7, 71:17, 79:4, 93:19, 95:7, 103:4, 113:15, 114:18, 119:3, 127:11, 151:13, 163:4, 164:9, 167:1, 167:14, 171:23, 174:21, 206:7, 229:20, 238:21</p> <p>al [4] - 1:7, 1:13, 250:6, 250:7</p> <p>alarm [1] - 179:20</p> <p>Alexander [2] - 128:1, 130:8</p> <p>allegations [6] - 33:5, 33:7, 33:9, 33:10, 71:13, 79:1</p> <p>alleged [12] - 16:8, 48:9, 48:11, 48:16, 68:24, 69:7, 69:14, 78:25, 80:19, 80:20, 81:8, 82:5</p> <p>alleges [2] - 47:5, 47:16</p> <p>allotment [1] - 201:13</p> <p>allotted [3] - 132:9, 138:5, 197:17</p> <p>allow [6] - 62:10, 86:21, 121:1, 157:3, 210:11, 247:13</p> <p>allowed [10] - 12:20, 42:25, 87:19, 110:22, 127:15, 128:2, 153:24, 197:16, 217:14, 239:17</p> <p>Allowing [1] - 70:24</p> <p>allowing [2] - 71:1, 129:12</p> <p>allows [1] - 198:25</p> <p>almost [4] - 21:13, 122:15, 144:2, 202:22</p>	<p>aloud [1] - 92:16</p> <p>Alprazolam [2] - 25:25</p> <p>alter [1] - 129:8</p> <p>amend [1] - 150:19</p> <p>AmerisourceBergen [19] - 6:2, 58:25, 59:3, 59:5, 59:15, 60:24, 61:12, 61:25, 67:10, 68:13, 69:7, 69:11, 70:10, 71:10, 72:7, 72:10, 72:12, 104:7, 250:6</p> <p>AMERISOURCEBERGEN [2] - 1:7, 1:13</p> <p>AmerisourceBergen's [8] - 53:22, 61:13, 62:13, 62:22, 63:22, 64:7, 66:4, 72:14</p> <p>amount [13] - 23:15, 131:11, 134:4, 135:2, 160:25, 196:18, 197:1, 197:22, 197:24, 199:6, 199:7, 201:18</p> <p>amounts [2] - 25:13, 67:12</p> <p>ample [1] - 56:12</p> <p>analysis [1] - 235:15</p> <p>ANDREW [1] - 5:10</p> <p>ANNE [1] - 4:2</p> <p>ANNIE [1] - 3:14</p> <p>annual [3] - 208:9, 210:24, 211:2</p> <p>anomalies [3] - 186:13, 186:19, 186:21</p> <p>anomaly [1] - 161:2</p> <p>anonymously [1] - 190:19</p> <p>answer [60] - 8:13, 8:17, 13:17, 15:6, 15:8, 17:23, 20:4, 23:7, 28:5, 30:14, 40:9, 41:15, 41:19, 49:22, 50:8, 50:16, 52:3, 52:4, 52:6, 62:10, 63:7, 64:1, 64:3, 64:11, 66:20, 71:4, 79:5, 83:9, 104:22, 106:2, 106:10, 107:4, 107:8, 111:13, 111:16, 112:10, 112:16, 113:15, 114:17, 121:1, 130:10, 146:23, 147:12, 169:3, 169:20, 170:20, 170:23, 171:22, 174:20, 178:19,</p>	<p>178:22, 203:24, 205:18, 213:15, 229:18, 229:20, 230:10, 237:25, 241:16</p> <p>answered [3] - 41:4, 102:22, 164:23</p> <p>answering [1] - 102:4</p> <p>answers [2] - 98:9, 106:6</p> <p>Anthony [1] - 209:6</p> <p>ANTHONY [1] - 2:6</p> <p>anti [3] - 62:14, 62:24, 207:24</p> <p>anti-addiction [1] - 207:24</p> <p>anti-diversion [2] - 62:14, 62:24</p> <p>anticipated [2] - 125:24, 126:17</p> <p>anytime [1] - 153:22</p> <p>anyway [2] - 104:8, 151:1</p> <p>apologize [8] - 44:22, 50:17, 87:10, 107:10, 114:20, 161:24, 169:17, 178:16</p> <p>appear [6] - 28:20, 29:8, 31:16, 193:4, 194:22, 235:21</p> <p>APPEARANCES [6] - 2:1, 3:1, 5:1, 5:6, 6:1, 6:10</p> <p>Appendices [1] - 80:19</p> <p>Appendix [4] - 80:23, 81:1, 81:2, 81:7</p> <p>applied [1] - 29:24</p> <p>apply [1] - 101:1</p> <p>appreciate [1] - 122:9</p> <p>approach [21] - 10:4, 32:1, 44:6, 59:8, 68:5, 72:21, 84:18, 92:13, 108:21, 109:10, 116:8, 124:17, 139:3, 148:5, 153:4, 154:11, 166:3, 187:6, 192:5, 219:1, 224:20</p> <p>appropriate [7] - 63:13, 84:9, 95:24, 117:13, 117:16, 117:23, 159:25</p> <p>appropriately [6] - 182:6, 182:9, 184:19, 184:23, 185:1, 229:15</p> <p>approval [13] - 48:24,</p>	<p>53:15, 53:22, 53:25, 54:3, 55:2, 57:1, 58:16, 89:9, 148:20, 148:23, 182:13, 182:16</p> <p>approve [10] - 21:14, 52:24, 55:7, 89:4, 115:24, 140:13, 140:16, 144:20, 182:11, 182:19</p> <p>approved [6] - 52:17, 54:23, 119:10, 142:7, 143:24, 148:20</p> <p>approves [1] - 21:3</p> <p>approving [3] - 50:13, 51:5, 52:22</p> <p>April [4] - 59:17, 139:19, 213:4, 213:9</p> <p>Arch [2] - 6:6, 6:13</p> <p>ARCOS [45] - 8:4, 9:4, 13:13, 16:6, 36:20, 39:17, 118:18, 156:12, 156:14, 156:15, 156:18, 156:21, 157:9, 157:11, 157:14, 157:19, 157:20, 157:25, 158:5, 158:22, 158:25, 160:17, 167:19, 167:21, 167:23, 168:1, 168:4, 168:11, 168:18, 168:20, 169:14, 169:25, 170:4, 170:9, 217:8, 217:11, 217:13, 232:5, 233:13, 234:8, 234:17, 235:3, 235:8, 235:10, 235:15</p> <p>area [11] - 11:16, 11:21, 23:13, 24:25, 26:18, 50:2, 133:7, 164:6, 176:5, 176:21, 195:5</p> <p>areas [7] - 49:19, 132:24, 133:1, 165:8, 166:2, 174:14, 176:20</p> <p>arena [1] - 163:15</p> <p>argue [3] - 34:2, 38:14, 49:21</p> <p>arguing [2] - 33:22, 229:18</p> <p>argument [4] - 56:13, 101:1, 115:9, 126:12</p> <p>arose [1] - 215:6</p> <p>Arpaio [2] - 95:14</p>	<p>artfully [1] - 102:3</p> <p>articulated [1] - 130:21</p> <p>ASHLEY [1] - 5:3</p> <p>aside [7] - 58:19, 96:23, 101:10, 147:21, 166:10, 167:18, 192:1</p> <p>aspects [3] - 87:19, 114:2, 154:20</p> <p>asserted [1] - 223:22</p> <p>assertion [1] - 222:17</p> <p>assessment [2] - 90:1, 196:21</p> <p>assist [1] - 113:4</p> <p>Assistant [16] - 30:10, 31:6, 57:14, 72:8, 102:15, 156:17, 160:4, 162:20, 180:20, 181:20, 183:13, 186:24, 195:9, 198:6, 204:17, 205:7</p> <p>assistant [2] - 99:5, 99:6</p> <p>Association [1] - 97:13</p> <p>assume [6] - 65:10, 79:20, 79:21, 165:19, 193:25, 216:5</p> <p>assuming [1] - 164:12</p> <p>assumption [2] - 106:15, 106:20</p> <p>assure [1] - 75:23</p> <p>AT [1] - 1:2</p> <p>attached [2] - 28:15, 148:21</p> <p>attachment [1] - 76:2</p> <p>attempted [1] - 114:14</p> <p>attempting [1] - 87:21</p> <p>attempts [1] - 151:15</p> <p>attend [3] - 212:11, 212:15, 247:6</p> <p>attended [2] - 194:22, 212:13</p> <p>attending [2] - 99:13, 195:1</p> <p>attention [6] - 84:5, 120:8, 145:8, 150:4, 151:11, 176:3</p> <p>attitude [1] - 141:2</p> <p>attorney [2] - 8:14, 49:15</p> <p>attorney-client [2] - 8:14, 49:15</p> <p>attorney/client [2] - 106:6, 120:22</p> <p>attorneys [1] - 23:15</p> <p>Auburn [2] - 73:18,</p>
--	--	---	---	--

<p>77:4 audit [4] - 179:18, 179:19, 180:4, 180:5 audits [1] - 231:4 augment [2] - 235:5, 235:8 August [5] - 35:18, 36:13, 60:16, 60:18, 60:23 authority [5] - 101:25, 117:4, 117:22, 148:16, 151:22 authorization [3] - 42:15, 42:20, 42:24 authorized [3] - 32:20, 42:17, 88:6 Automation [1] - 69:11 available [8] - 149:22, 149:25, 159:14, 159:17, 166:11, 167:10, 170:16, 198:11 average [3] - 125:2, 247:15, 247:20 Avin [1] - 3:7 avoid [1] - 118:7 aware [31] - 63:14, 63:15, 84:21, 96:2, 97:3, 97:6, 103:10, 111:7, 136:3, 169:4, 169:7, 169:9, 173:20, 183:1, 183:4, 215:18, 216:20, 217:19, 228:23, 229:1, 237:20, 238:2, 238:6, 238:7, 238:8, 238:23, 239:15, 239:17, 239:23, 240:16, 243:20 Awareness [1] - 192:12 awful [1] - 185:23 Ayme [2] - 6:17, 250:2</p>	<p>base [3] - 120:4, 196:24, 203:15 based [29] - 8:14, 19:17, 20:10, 39:10, 43:25, 54:16, 55:8, 63:5, 63:9, 66:6, 71:18, 71:23, 82:4, 104:5, 112:9, 128:4, 158:10, 163:17, 168:11, 171:6, 182:7, 183:12, 184:18, 202:24, 202:25, 203:25, 216:3, 242:21 Based [2] - 216:3, 242:21 basic [1] - 18:10 basics [1] - 210:4 basis [25] - 11:25, 20:1, 27:5, 39:24, 40:25, 51:14, 51:22, 54:6, 54:13, 56:20, 57:1, 62:3, 64:2, 66:10, 66:15, 86:19, 88:15, 98:17, 100:11, 109:20, 118:10, 151:6, 197:13, 205:14, 208:10 Bates [6] - 73:2, 73:4, 85:24, 192:24, 193:20 battles [1] - 128:15 Baylen [1] - 2:13 bear [1] - 7:18 become [1] - 186:11 BEFORE [1] - 1:17 began [2] - 145:21, 221:5 begin [1] - 129:3 beginning [4] - 57:10, 140:8, 145:15, 190:13 begins [1] - 139:7 behalf [7] - 42:9, 42:11, 99:23, 106:4, 191:16, 209:6 behavior [1] - 204:11 behind [4] - 24:23, 115:9, 170:4, 235:16 belief [3] - 39:10, 51:5, 52:15 bell [1] - 175:12 bellwether [1] - 128:20 below [1] - 47:12 BENCH [1] - 1:16 benefit [2] - 132:14, 134:19 benzodiazepines [1] -</p>	<p>69:13 best [1] - 34:24 better [1] - 106:22 Between [1] - 68:12 between [31] - 10:13, 13:21, 14:7, 14:8, 15:10, 15:12, 15:17, 15:21, 16:7, 20:20, 21:9, 44:13, 46:13, 79:15, 80:5, 91:18, 93:2, 93:22, 94:10, 97:3, 98:11, 98:25, 166:22, 174:13, 202:2, 218:11, 219:6, 219:20, 220:9, 220:15 beyond [5] - 79:12, 126:16, 172:18, 181:11, 238:18 Bi [7] - 225:18, 225:24, 226:10, 226:12, 226:24, 227:3, 228:11 Bi-Wise [7] - 225:18, 225:24, 226:10, 226:12, 226:24, 227:3, 228:11 bias [2] - 208:23, 209:1 big [6] - 18:19, 23:23, 43:17, 96:5, 115:9, 192:3 Bill [1] - 237:8 bit [7] - 41:9, 133:14, 134:15, 136:23, 179:15, 185:23, 211:7 black [1] - 14:21 blacked [5] - 224:12, 224:15, 229:4, 229:6, 229:7 blackened-out [1] - 224:12 blackout [1] - 225:3 bleed [1] - 127:16 blind [1] - 119:1 blinders [1] - 238:10 block [2] - 115:5, 226:15 blood [1] - 128:10 Blue [2] - 24:11, 24:18 blue [2] - 24:15, 24:16 Blvd [3] - 3:15, 4:3, 4:9 board [5] - 21:5, 21:16, 97:23, 158:12, 226:9 bogged [1] - 135:19 bogging [1] - 125:5 Boggs [6] - 99:8,</p>	<p>99:10, 99:18, 100:11, 100:15, 101:4 Bonasso [1] - 5:14 bones [1] - 123:21 bootstrap [1] - 38:6 bore [1] - 60:22 bottle [2] - 35:22, 35:23 bottom [13] - 14:3, 47:25, 118:3, 140:23, 226:15, 233:18, 233:19, 236:2, 239:7, 239:8, 242:3, 245:17, 248:13 Bottom [1] - 245:22 bought [1] - 166:23 Boulevard [1] - 3:18 bounds [1] - 12:24 bow [1] - 138:11 Box [2] - 5:14, 6:8 boxes [1] - 214:22 brand [1] - 18:18 breach [1] - 183:10 break [6] - 36:2, 65:22, 127:16, 127:20, 184:4, 201:10 breakdown [2] - 67:15, 82:6 breaks [1] - 34:13 brick [3] - 20:18, 20:21, 22:2 bridge [1] - 19:24 Bridgeside [3] - 3:15, 4:3, 4:9 Brief [1] - 151:20 brief [6] - 8:2, 245:6, 245:11, 245:13, 245:14, 245:15 briefed [10] - 31:14, 39:25, 40:14, 57:13, 57:20, 85:5, 85:7, 244:19, 244:20, 245:4 briefing [2] - 103:12, 245:14 briefings [9] - 7:21, 19:18, 82:12, 105:14, 109:18, 110:17, 212:16, 245:7, 245:14 briefly [5] - 20:20, 102:12, 108:2, 138:25, 196:16 bring [1] - 72:6 bringing [1] - 55:4 brings [3] - 145:8, 152:24, 152:25</p>	<p>broad [1] - 211:21 broader [1] - 38:7 brought [1] - 176:3 Budd [1] - 3:17 budget [1] - 210:24 building [1] - 106:19 bullet [6] - 16:4, 155:16, 155:18, 225:4, 227:24, 232:12 bulletin [2] - 21:5, 21:16 bullets [1] - 14:3 bunch [1] - 137:17 burden [1] - 122:18 Burling [1] - 5:11 bus [1] - 24:6 business [6] - 151:5, 151:19, 202:18, 223:25, 225:17, 230:2 butress [1] - 53:24 buying [1] - 160:21 BY [149] - 7:15, 9:2, 10:6, 12:3, 12:25, 13:10, 15:7, 16:3, 18:5, 19:12, 20:6, 23:6, 26:21, 27:8, 27:18, 28:9, 32:3, 35:15, 36:10, 39:2, 41:5, 41:16, 43:15, 44:7, 46:15, 46:23, 47:2, 50:7, 51:1, 51:17, 51:23, 54:15, 57:8, 59:10, 62:11, 62:21, 63:17, 65:15, 67:7, 68:3, 68:7, 69:25, 70:8, 70:20, 71:8, 72:5, 72:22, 73:7, 76:25, 79:6, 79:25, 81:23, 82:7, 83:14, 84:16, 84:19, 85:17, 88:2, 89:2, 90:12, 91:2, 92:14, 92:23, 94:7, 96:1, 98:23, 99:17, 99:22, 101:8, 101:18, 102:10, 103:9, 104:25, 105:15, 107:20, 108:13, 109:1, 109:12, 109:24, 110:15, 111:5, 111:25, 112:24, 113:11, 113:14, 113:19, 114:22, 115:12, 116:14, 121:12, 121:24, 138:24, 139:4, 142:18, 143:5, 143:18,</p>
B				
<p>background [1] - 123:7 backtrack [1] - 170:7 baked [1] - 106:15 balance [1] - 136:17 balances [1] - 135:11 balancing [2] - 201:8 bang [1] - 192:3 bare [1] - 123:21 Baron [1] - 3:17 Barrett [2] - 128:1, 130:8</p>				

146:11, 147:2, 147:15, 151:2, 153:5, 154:12, 155:14, 156:1, 158:14, 160:2, 160:9, 161:12, 162:13, 163:7, 164:21, 167:17, 169:23, 171:2, 171:24, 173:19, 174:24, 175:11, 176:11, 183:21, 184:11, 185:16, 187:7, 188:21, 190:4, 190:11, 191:25, 192:7, 195:7, 195:21, 196:12, 204:3, 205:17, 206:13, 206:25, 207:10, 209:23, 210:3, 213:6, 214:17, 218:9, 219:4, 219:17, 224:9, 224:22, 225:14, 229:25, 238:22, 241:25	Cardinal [46] - 4:11, 5:2, 73:18, 74:2, 74:10, 74:22, 75:17, 76:3, 76:21, 77:13, 78:2, 78:12, 78:16, 79:15, 80:6, 80:20, 81:8, 84:14, 85:20, 86:6, 89:16, 89:20, 90:6, 90:7, 90:17, 91:3, 91:20, 92:5, 93:2, 93:23, 94:1, 94:10, 94:19, 96:2, 96:20, 104:6, 108:17, 142:5, 142:13, 143:3, 143:13, 206:1, 206:4, 212:12, 212:16 Cardinal's [7] - 78:22, 78:23, 81:13, 89:15, 89:19, 89:23, 90:2 care [8] - 22:9, 119:7, 134:7, 164:18, 200:2, 200:16, 201:2, 201:3 career [2] - 204:23, 230:21 careful [1] - 165:20 carefully [1] - 64:1 Carey [1] - 4:17 Carisoprodol [1] - 26:2 Carolina [1] - 127:9 carry [1] - 245:17 carry-over [1] - 245:17 carrying [2] - 180:21, 193:14 case [44] - 17:20, 21:3, 33:19, 34:7, 65:7, 81:21, 122:18, 123:17, 123:20, 123:22, 124:23, 124:25, 125:25, 126:6, 126:8, 126:10, 126:13, 126:21, 127:14, 127:22, 128:6, 128:7, 128:8, 128:13, 128:22, 129:13, 131:4, 133:18, 135:6, 137:5, 137:7, 137:21, 142:5, 147:24, 148:1, 164:12, 165:11, 166:6, 188:15, 194:15, 228:20 cases [8] - 21:11, 21:13, 117:23, 121:6, 132:4,	161:19, 162:1, 164:2 cash [5] - 22:12, 161:4, 161:23, 162:16, 163:15 catch [2] - 85:10, 90:11 categorical [1] - 162:7 Caucus [1] - 189:4 caught [1] - 235:24 caused [2] - 51:4, 202:21 causing [1] - 31:11 caveat [2] - 43:2, 81:21 ceiling [3] - 183:7, 183:8, 183:9 Center [15] - 3:12, 5:11, 15:23, 37:15, 37:19, 38:1, 39:7, 39:8, 39:13, 46:2, 46:10, 47:4, 47:7, 47:18, 61:13 center [21] - 20:23, 21:4, 21:16, 38:5, 39:18, 39:21, 43:21, 44:1, 44:3, 46:4, 58:17, 62:6, 77:14, 90:7, 90:18, 220:12, 231:11, 239:21, 239:25, 244:9 Centers [1] - 47:23 centers [18] - 43:22, 43:23, 44:1, 44:25, 45:15, 81:3, 81:13, 110:7, 110:9, 176:13, 177:17, 180:23, 181:3, 181:11, 212:25, 213:14, 243:21, 244:16 central [2] - 45:20, 221:1 centralized [3] - 231:15, 231:16, 231:18 centrally [5] - 45:10, 45:14, 45:15, 45:17, 45:22 certain [17] - 41:12, 47:10, 47:20, 87:19, 105:17, 111:23, 118:17, 154:20, 158:15, 158:17, 165:23, 168:11, 174:16, 180:4, 199:16, 214:13, 220:11 certainly [5] - 49:18, 54:11, 85:16, 114:14, 132:6	CERTIFICATION [1] - 250:1 certify [2] - 198:17, 250:4 cetera [2] - 91:8, 165:2 chain [7] - 89:20, 94:16, 95:5, 95:10, 96:21, 170:8, 204:8 challenge [3] - 91:20, 165:14, 169:19 challenges [4] - 233:22, 233:23, 233:25 chance [6] - 52:9, 62:12, 62:22, 125:4, 156:13, 195:10 chances [1] - 18:22 change [10] - 130:21, 147:18, 202:3, 202:13, 202:18, 205:8, 205:11, 216:4, 216:16, 240:13 changed [9] - 129:8, 177:2, 177:5, 205:9, 215:21, 216:10, 216:15, 240:8, 240:17 changes [1] - 240:14 channels [4] - 47:9, 47:20, 89:18, 118:9 characteristics [1] - 60:22 characterization [4] - 78:25, 105:5, 109:19, 120:17 characterizing [1] - 236:8 charge [2] - 197:10, 201:5 Chargeback [2] - 163:9, 163:11 charged [1] - 210:5 CHARLES [1] - 3:11 CHARLESTON [2] - 1:2, 1:18 Charleston [6] - 2:8, 3:13, 4:19, 5:15, 6:9, 7:4 Chase [1] - 4:18 check [3] - 7:23, 216:2, 240:2 checking [1] - 238:12 chemicals [1] - 247:5 cherry [1] - 33:9 cherry-picked [1] - 33:9 Chesterbrook [1] - 6:15 Chief [4] - 11:3, 15:17,	154:19, 161:14 chief [1] - 138:18 children [1] - 190:21 choice [1] - 126:5 choices [7] - 129:14, 129:15, 130:13, 132:3, 132:10, 134:19, 136:15 choke [3] - 228:6, 228:8, 228:18 choose [2] - 210:10, 234:3 chop [2] - 149:7, 149:8 chopped [2] - 61:18, 148:20 chopped" [1] - 148:24 chronic [3] - 200:16, 239:16, 239:20 CII [1] - 247:16 circulate [2] - 148:3, 153:3 circulation [1] - 98:7 circumstance [1] - 130:22 circumstances [4] - 118:10, 119:2, 129:8, 181:21 circumvent [1] - 206:6 citation [1] - 151:23 cite [2] - 34:2, 188:14 cites [1] - 75:20 City [3] - 4:1, 5:11, 250:5 CITY [1] - 1:4 Civil [3] - 1:4, 250:7, 250:8 civil [1] - 1:10 claim [1] - 49:21 clandestine [1] - 247:9 clarification [1] - 110:14 clarifies [1] - 214:9 clarify [2] - 90:20, 116:11 clarity [1] - 137:25 class [1] - 18:10 clear [16] - 11:15, 14:13, 41:20, 42:16, 50:24, 52:22, 54:16, 67:5, 105:13, 113:24, 129:6, 129:9, 132:2, 137:6, 137:12, 240:5 clearly [5] - 131:6, 191:4, 194:19, 223:24, 229:18 clerk [2] - 86:23, 138:18
C	C.F.R [3] - 69:17, 81:10, 89:22 CA [1] - 3:18 Cabell [7] - 3:2, 26:9, 34:19, 38:5, 209:7, 216:19, 216:21 CABELL [1] - 1:10 cabell [1] - 2:2 Cabell-Huntington [1] - 26:9 Cabell/Huntington [2] - 88:22 cabinet [2] - 190:22, 191:3 cabinets [1] - 191:9 cage [1] - 179:20 calculus [1] - 129:8 CALLAS [1] - 6:7 CAMPBELL [1] - 6:14 cannot [2] - 107:16, 169:2 capacity [5] - 161:13, 162:20, 187:15, 189:8, 204:18 Capital [1] - 188:15 Capitol [1] - 2:7 capture [1] - 245:14 captured [1] - 179:10 car [1] - 24:6 card [1] - 55:19			

<p>client [3] - 8:14, 49:15, 194:22</p> <p>client's [1] - 205:14</p> <p>clients [1] - 128:21</p> <p>clinic [4] - 22:6, 22:7, 22:8, 23:3</p> <p>clinics [3] - 22:5, 23:9</p> <p>clock [1] - 136:2</p> <p>close [2] - 176:8, 227:22</p> <p>closed [5] - 210:5, 210:11, 210:13, 210:15, 211:16</p> <p>closeout [4] - 180:9, 180:11, 180:12, 180:16</p> <p>closer [1] - 97:12</p> <p>Cochran [3] - 6:17, 250:2, 250:11</p> <p>code [2] - 196:24, 203:15</p> <p>Code [2] - 179:21, 179:22</p> <p>coincidental [1] - 117:4</p> <p>college [1] - 205:2</p> <p>Colorado [1] - 47:17</p> <p>Columbia [1] - 91:23</p> <p>column [2] - 124:11, 124:12</p> <p>coming [8] - 22:22, 25:12, 35:9, 40:11, 75:15, 122:9, 137:11</p> <p>commerce [2] - 11:3, 16:6</p> <p>COMMISSION [1] - 1:10</p> <p>Commission [2] - 2:2, 3:2</p> <p>commitment [4] - 23:23, 41:23, 43:17, 43:19</p> <p>committed [1] - 65:3</p> <p>communicate [2] - 25:16, 182:18</p> <p>communicated [3] - 91:3, 100:7, 100:18</p> <p>communication [4] - 15:21, 93:22, 100:23, 101:2</p> <p>communications [17] - 8:15, 13:23, 14:7, 15:11, 15:16, 15:18, 27:21, 91:6, 91:7, 91:9, 91:13, 92:9, 93:1, 93:6, 93:23, 141:20, 182:21</p> <p>community [4] - 133:15, 169:9, 205:11, 218:15</p>	<p>companies [2] - 174:23, 199:18</p> <p>company [8] - 54:22, 105:22, 109:6, 163:14, 175:2, 206:9, 226:19, 231:2</p> <p>compare [1] - 208:9</p> <p>compared [1] - 161:1</p> <p>comparing [1] - 95:23</p> <p>comparison [1] - 163:17</p> <p>competing [1] - 200:22</p> <p>competitors [1] - 169:6</p> <p>complaints [1] - 146:19</p> <p>completed [3] - 170:6, 245:19, 246:3</p> <p>completeness [1] - 214:10</p> <p>complex [1] - 126:21</p> <p>complexity [1] - 127:13</p> <p>compliance [18] - 18:20, 19:15, 37:8, 45:9, 45:20, 58:3, 58:11, 58:16, 62:13, 62:23, 63:23, 66:4, 72:14, 96:20, 161:16, 178:2, 181:23, 209:3</p> <p>Compliance [1] - 204:7</p> <p>compliant [6] - 19:4, 37:10, 72:17, 72:18, 179:20, 179:22</p> <p>complies [1] - 140:21</p> <p>comply [2] - 39:19, 206:18</p> <p>complying [3] - 145:18, 175:20, 206:17</p> <p>composite [2] - 72:25, 87:18</p> <p>compromising [1] - 175:5</p> <p>computer [1] - 6:19</p> <p>concentrate [1] - 160:15</p> <p>concentrated [1] - 23:12</p> <p>concept [4] - 24:14, 24:15, 119:19, 228:5</p> <p>concern [2] - 83:16, 186:4</p> <p>concerned [2] - 143:10, 221:12</p> <p>concerning [2] - 13:13, 116:24</p>	<p>concerns [9] - 169:4, 169:7, 169:8, 175:1, 175:5, 217:7, 217:15, 220:10, 221:6</p> <p>concluded [2] - 61:10, 81:12</p> <p>conclusion [15] - 19:3, 30:16, 64:19, 65:2, 65:5, 65:13, 65:19, 81:16, 102:20, 126:20, 146:6, 147:9, 173:16, 206:22, 239:10</p> <p>conditionally [3] - 87:12, 87:24, 88:25</p> <p>Conduct [3] - 68:22, 80:15, 80:17</p> <p>conduct [30] - 48:1, 48:6, 48:7, 48:8, 60:7, 61:6, 61:20, 63:22, 67:10, 68:24, 69:21, 70:2, 70:9, 70:22, 71:9, 80:18, 81:7, 81:24, 82:4, 82:5, 82:10, 84:7, 89:16, 89:19, 89:23, 151:15, 158:5</p> <p>conducted [2] - 94:16, 141:10</p> <p>conducting [5] - 173:20, 179:12, 181:2, 199:18, 199:19</p> <p>confer [1] - 58:11</p> <p>conference [8] - 129:4, 152:21, 153:22, 153:23, 192:15, 194:23, 195:1</p> <p>Conference [2] - 152:24, 192:13</p> <p>conferences [6] - 28:7, 152:18, 153:11, 154:19, 155:3</p> <p>conferred [1] - 75:12</p> <p>confidential [3] - 166:13, 169:5, 175:6</p> <p>confines [1] - 64:15</p> <p>confirm [1] - 182:7</p> <p>confirming [1] - 119:7</p> <p>conform [1] - 119:14</p> <p>conforming [1] - 119:15</p> <p>Congress [13] - 22:1, 186:25, 187:20, 189:5, 189:12, 191:15, 197:3,</p>	<p>197:6, 197:10, 198:2, 215:12, 234:13, 235:20</p> <p>congressional [1] - 188:16</p> <p>connection [1] - 92:1</p> <p>Connolly [2] - 4:13, 5:4</p> <p>Conroe [7] - 46:10, 46:18, 47:3, 47:6, 47:7, 47:12</p> <p>CONROY [1] - 3:3</p> <p>consequences [1] - 117:19</p> <p>consider [7] - 87:15, 147:3, 147:11, 147:14, 148:13, 167:3, 167:16</p> <p>considered [1] - 18:7</p> <p>considering [1] - 43:9</p> <p>consistent [7] - 50:8, 56:2, 57:16, 121:19, 152:12, 156:8, 184:23</p> <p>consistently [1] - 34:9</p> <p>Consolidated [1] - 69:12</p> <p>constitutes [2] - 172:16, 172:25</p> <p>constraint [1] - 134:19</p> <p>consult [1] - 98:8</p> <p>consultant [2] - 207:12, 208:4</p> <p>consulting [1] - 207:17</p> <p>contact [1] - 94:18</p> <p>contained [2] - 15:2, 87:2</p> <p>container [1] - 157:17</p> <p>contains [1] - 211:13</p> <p>contemporaneous [1] - 223:25</p> <p>content [1] - 91:17</p> <p>contested [4] - 114:5, 114:11, 114:13, 241:7</p> <p>continuation [1] - 61:7</p> <p>continue [12] - 28:25, 31:15, 31:17, 60:25, 71:12, 92:21, 115:17, 123:16, 152:8, 199:25, 221:8, 242:7</p> <p>Continued [5] - 3:1, 5:1, 5:6, 6:1, 6:10</p> <p>continued [9] - 9:12, 39:20, 182:25, 206:18, 206:19, 218:14, 228:13,</p>	<p>228:14</p> <p>continues [1] - 42:10</p> <p>continuing [6] - 13:14, 13:18, 36:25, 42:8, 79:21, 208:1</p> <p>contrary [4] - 105:23, 223:9, 223:11, 239:19</p> <p>contrast [1] - 191:4</p> <p>contributes [1] - 190:20</p> <p>contributors [1] - 159:4</p> <p>control [3] - 125:7, 125:21, 135:22</p> <p>Control [5] - 189:4, 204:19, 210:21, 211:23, 214:20</p> <p>Controlled [15] - 60:8, 62:13, 62:23, 72:14, 115:22, 116:4, 116:25, 121:16, 144:9, 154:20, 171:14, 171:18, 203:14, 204:7, 234:4</p> <p>controlled [67] - 9:13, 18:17, 29:6, 29:8, 47:8, 47:19, 48:12, 48:14, 48:17, 61:12, 69:8, 69:10, 69:13, 69:15, 69:18, 78:23, 79:9, 80:21, 80:24, 81:9, 81:13, 84:8, 89:14, 89:17, 104:15, 105:3, 118:17, 120:13, 121:9, 140:17, 140:22, 141:8, 141:12, 153:2, 158:22, 158:24, 159:5, 159:8, 159:9, 159:13, 160:11, 160:14, 160:15, 160:17, 160:21, 160:22, 165:1, 184:15, 190:17, 190:18, 190:22, 190:25, 196:17, 201:24, 202:4, 202:8, 202:10, 203:11, 220:11, 220:25, 222:19, 234:11, 234:20, 247:5, 247:17, 247:21</p> <p>controls [16] - 30:8, 46:10, 47:6, 47:17, 48:12, 69:8, 80:21, 118:23, 119:5, 152:10, 161:1,</p>
---	---	---	---	--

177:21, 180:24, 181:1, 181:4 convenient [1] - 184:7 conversation [2] - 99:10, 102:14 conversations [1] - 174:10 convey [6] - 99:19, 99:20, 100:6, 101:22, 105:2, 180:7 conveyed [2] - 98:12, 101:19 conveying [3] - 101:21, 187:20, 189:12 Cook [3] - 6:18, 250:3, 250:11 cooperation [1] - 246:24 cooperative [1] - 211:15 coordinate [1] - 132:4 coordinator [1] - 247:9 cop [1] - 20:25 copies [2] - 108:24, 219:11 copy [6] - 43:8, 43:11, 124:17, 220:3, 221:15, 224:10 corners [1] - 30:24 Corporation [5] - 6:2, 37:21, 220:9, 236:4, 250:7 cORPORATION [2] - 1:7, 1:13 correct [80] - 16:19, 47:12, 47:23, 50:14, 51:7, 51:11, 59:19, 77:4, 108:11, 149:4, 159:19, 184:16, 210:6, 210:7, 210:8, 210:11, 210:12, 210:16, 210:17, 210:25, 211:1, 211:2, 211:5, 211:6, 211:18, 211:24, 212:1, 212:4, 212:5, 212:17, 212:18, 212:22, 212:25, 213:1, 213:14, 213:15, 213:20, 213:22, 214:20, 214:24, 214:25, 215:2, 215:3, 215:6, 215:9, 215:13, 215:17, 217:2, 217:5, 217:6, 217:8, 217:12, 217:15, 218:15, 220:15,	221:20, 222:7, 223:9, 226:22, 226:23, 227:3, 227:8, 228:10, 228:14, 228:20, 229:3, 230:3, 230:22, 231:2, 231:8, 234:23, 235:12, 236:9, 238:24, 240:6, 240:9, 240:14, 245:12, 248:18, 250:4 Correct [2] - 221:17, 228:18 corrections [1] - 63:13 correctly [5] - 56:25, 151:24, 213:16, 222:21, 232:17 Corridor [2] - 24:8, 24:22 counsel [4] - 15:17, 34:19, 214:2, 221:11 Counsel [1] - 154:19 count [5] - 134:13, 135:9, 135:12, 136:13, 136:17 counter [2] - 135:2, 234:1 counter-designation [1] - 135:2 country [6] - 25:21, 45:6, 67:17, 128:21, 197:9, 203:17 COUNTY [1] - 1:10 County [6] - 2:2, 3:2, 34:19, 209:7, 216:19, 216:21 couple [9] - 76:7, 110:11, 123:14, 127:17, 127:25, 128:1, 136:1, 210:18, 220:23 COUR [1] - 27:17 course [8] - 15:14, 53:9, 123:8, 127:6, 186:3, 205:6, 236:3 Court [39] - 6:17, 6:18, 7:3, 43:7, 43:9, 65:24, 73:20, 73:23, 75:23, 79:20, 86:12, 87:10, 91:22, 123:6, 125:14, 129:3, 129:9, 129:12, 129:16, 129:20, 130:2, 130:15, 130:25, 131:16, 132:2, 132:9, 132:14, 133:13, 133:14, 134:5,	134:12, 145:4, 150:20, 150:23, 196:17, 224:12, 250:2, 250:3 COURT [270] - 1:1, 1:17, 7:6, 7:9, 7:13, 8:10, 8:19, 8:21, 9:1, 10:5, 10:19, 11:13, 11:17, 12:1, 12:15, 12:22, 13:6, 14:13, 15:5, 17:22, 19:8, 20:3, 23:1, 23:4, 26:5, 26:14, 27:5, 27:10, 27:12, 27:15, 28:3, 32:2, 33:12, 33:16, 33:25, 34:6, 34:17, 34:20, 35:3, 35:7, 35:10, 35:13, 35:23, 36:1, 36:5, 36:9, 38:8, 38:10, 38:12, 38:25, 39:22, 40:10, 40:21, 41:3, 41:18, 41:24, 42:6, 42:12, 42:21, 43:5, 43:11, 46:25, 49:12, 50:1, 50:20, 50:23, 51:16, 51:19, 51:22, 52:8, 53:4, 53:20, 55:11, 55:18, 55:22, 56:15, 56:21, 56:25, 57:21, 59:9, 62:9, 62:17, 62:25, 63:7, 64:10, 64:25, 65:6, 65:9, 65:12, 66:19, 67:5, 67:18, 67:20, 68:2, 68:6, 69:24, 70:7, 70:13, 70:17, 71:6, 71:16, 71:20, 72:4, 74:6, 74:18, 75:9, 76:5, 76:15, 76:23, 79:4, 79:23, 81:17, 82:3, 83:6, 84:11, 84:15, 85:12, 86:8, 86:23, 87:6, 87:12, 88:1, 88:13, 88:18, 90:9, 90:23, 92:19, 93:7, 93:12, 93:19, 94:5, 94:22, 95:2, 95:19, 98:21, 100:1, 100:9, 100:18, 101:5, 101:15, 102:8, 102:21, 102:23, 103:1, 103:3, 103:7, 104:24, 105:10, 105:24, 106:9, 106:24, 107:1, 107:8, 107:13, 107:19, 108:22, 109:11, 109:22, 111:1, 111:14,	112:12, 113:13, 113:16, 114:17, 115:7, 120:25, 121:22, 122:1, 122:4, 122:7, 124:2, 124:14, 124:18, 125:17, 127:7, 128:13, 128:24, 131:18, 131:23, 132:21, 133:3, 133:9, 133:22, 134:6, 135:25, 136:9, 136:19, 137:22, 138:4, 138:11, 143:8, 143:17, 145:7, 146:8, 146:22, 147:10, 150:14, 150:16, 150:25, 154:4, 154:9, 155:9, 155:13, 155:25, 159:24, 161:9, 162:11, 163:3, 164:8, 164:17, 165:15, 165:21, 167:1, 167:14, 169:21, 170:18, 170:20, 171:21, 173:18, 174:15, 175:10, 176:7, 178:19, 183:20, 184:4, 184:6, 184:10, 185:15, 188:2, 188:20, 189:20, 189:23, 190:2, 191:21, 192:6, 193:8, 193:16, 193:19, 193:23, 194:3, 194:5, 195:3, 195:20, 196:9, 203:24, 205:16, 206:21, 206:24, 207:7, 208:18, 209:4, 209:11, 209:16, 209:21, 210:1, 214:15, 218:8, 219:2, 223:14, 224:3, 224:7, 224:21, 225:11, 225:13, 229:20, 238:19, 241:23, 248:23, 248:25, 249:4 court [10] - 33:6, 33:7, 65:20, 75:21, 76:12, 136:16, 138:18, 188:4, 226:22, 238:17 Court's [8] - 13:11, 34:22, 75:2, 76:16,	129:5, 143:14, 158:11, 188:24 courtesy [1] - 115:6 Courtright [1] - 126:3 courtroom [1] - 26:9 courts [1] - 151:21 cover [6] - 82:10, 133:8, 136:21, 192:11, 195:14, 214:4 covered [9] - 48:1, 48:6, 48:7, 48:8, 80:18, 81:3, 165:23, 195:16, 215:5 Covered [4] - 68:22, 68:24, 80:15, 80:17 COVID [1] - 207:20 Covington [1] - 5:11 crack [1] - 196:2 crazy [1] - 18:1 create [2] - 41:12, 183:8 created [3] - 164:13, 180:15, 246:24 Crime [1] - 187:13 crisis [1] - 212:4 criteria [1] - 247:14 cross [13] - 41:15, 56:11, 125:1, 125:6, 126:1, 126:4, 132:6, 135:23, 138:18, 164:18, 209:8, 238:19, 238:20 CROSS [1] - 209:22 cross-examination [1] - 238:20 crosses [3] - 126:1, 131:14, 132:7 CRR [2] - 6:17, 6:18 CSA [2] - 141:10, 151:22 cull [3] - 212:14, 213:4, 226:10 cumulative [1] - 123:22 cure [3] - 27:24, 87:21, 223:18 cured [1] - 126:13 current [3] - 122:21, 175:5, 234:2 cursor [1] - 22:11 customer [8] - 120:4, 140:10, 151:8, 160:21, 160:25, 177:23, 186:18, 220:25 customer's [1] - 119:10 customers [30] - 47:10, 47:21, 89:16,
--	---	--	---	---

<p>89:20, 89:22, 90:6, 90:17, 104:8, 161:22, 162:16, 165:5, 173:4, 173:11, 173:22, 174:3, 174:4, 174:7, 174:13, 174:16, 222:9, 242:14, 242:16, 242:20, 242:23, 243:7, 244:3, 244:10, 244:17</p> <p>customers' [2] - 95:22, 151:4</p> <p>cut [17] - 76:23, 175:24, 200:20, 203:4, 217:25, 218:3, 222:2, 226:1, 226:25, 227:7, 227:22, 228:1, 228:13, 229:12, 230:3, 230:5, 230:6</p> <p>CVS [1] - 206:4</p> <p>cyberspace [1] - 20:23</p> <p>cycle [1] - 176:22</p> <p>cycles [1] - 176:20</p> <p>cyclic [7] - 176:18, 176:19, 177:10, 177:14, 177:19, 179:12, 181:12</p>	<p>164:23, 164:24, 166:10, 166:12, 166:15, 166:19, 167:5, 167:10, 167:19, 167:21, 167:23, 168:1, 168:4, 168:8, 168:11, 168:18, 168:20, 168:23, 168:24, 169:5, 169:10, 169:14, 170:9, 170:14, 217:8, 217:11, 217:13, 217:14, 217:16, 232:6, 233:13, 235:4, 235:8, 235:10, 235:17, 239:12</p> <p>database [1] - 235:3</p> <p>databases [2] - 165:24, 166:1</p> <p>date [17] - 36:11, 59:1, 59:16, 61:1, 61:3, 61:4, 68:19, 77:16, 78:3, 78:13, 131:10, 139:18, 142:19, 179:20, 192:17, 232:8, 232:11</p> <p>Date [1] - 250:16</p> <p>dated [1] - 139:19</p> <p>dates [2] - 50:19, 66:14</p> <p>David [1] - 7:1</p> <p>DAVID [2] - 1:17, 2:9</p> <p>Davies [1] - 123:18</p> <p>day-to-day [1] - 139:15</p> <p>days [17] - 16:24, 17:18, 17:24, 75:23, 103:21, 122:11, 123:8, 123:9, 123:10, 127:17, 128:6, 136:1, 177:13, 178:13, 228:12, 229:10, 229:11</p> <p>DC [7] - 2:11, 4:7, 4:14, 4:16, 5:5, 5:12, 244:3</p> <p>De [2] - 2:4, 2:16</p> <p>DEA [295] - 7:22, 10:13, 12:6, 12:18, 12:21, 13:3, 13:22, 14:7, 15:12, 15:17, 15:22, 20:15, 21:11, 23:8, 23:23, 24:1, 25:16, 25:22, 25:23, 26:7, 27:19, 28:23, 29:13, 29:14, 29:21, 29:24, 32:19, 35:16,</p>	<p>36:20, 37:2, 37:18, 39:12, 41:6, 41:7, 42:9, 42:10, 42:11, 43:17, 43:20, 44:13, 44:15, 46:14, 47:5, 47:16, 48:25, 49:5, 50:12, 51:2, 51:5, 52:17, 52:24, 53:15, 54:18, 54:23, 55:6, 55:24, 56:14, 57:10, 57:16, 58:4, 58:10, 58:11, 58:21, 58:24, 59:5, 59:22, 60:8, 60:23, 61:24, 62:12, 62:22, 68:16, 70:9, 72:6, 72:11, 72:13, 74:16, 74:19, 78:22, 79:15, 80:6, 80:12, 82:10, 83:23, 88:4, 91:3, 93:2, 93:23, 94:10, 94:15, 94:25, 95:17, 96:3, 96:17, 97:3, 97:6, 97:17, 98:11, 98:13, 98:25, 99:3, 99:19, 100:7, 100:18, 100:23, 101:10, 102:18, 103:11, 103:24, 108:17, 109:17, 110:6, 110:21, 111:7, 111:11, 111:13, 112:1, 112:2, 112:12, 112:14, 113:6, 113:8, 113:20, 114:2, 114:24, 115:17, 117:12, 117:20, 117:22, 117:25, 118:17, 118:25, 119:9, 119:12, 120:15, 121:1, 121:17, 121:20, 139:1, 139:16, 140:8, 140:9, 140:11, 140:13, 140:16, 140:21, 141:16, 144:22, 145:14, 146:13, 147:4, 147:12, 150:1, 150:4, 150:11, 151:16, 151:17, 151:21, 152:12, 152:17, 153:14, 153:16, 153:20, 153:22, 154:15, 155:2, 155:20, 156:3, 156:7, 156:14, 156:18, 157:12, 157:13, 157:18, 157:25,</p>	<p>158:4, 158:18, 158:20, 159:9, 159:18, 160:16, 162:18, 162:19, 165:6, 165:13, 166:11, 166:17, 167:8, 167:18, 167:23, 168:24, 169:24, 169:25, 170:11, 171:3, 171:4, 173:21, 174:2, 174:6, 174:7, 174:13, 174:19, 175:20, 176:12, 177:15, 177:19, 177:23, 177:25, 179:12, 180:6, 180:21, 181:3, 181:11, 181:13, 181:16, 181:19, 181:23, 182:1, 182:10, 182:18, 183:22, 184:16, 184:18, 185:17, 186:1, 186:4, 186:9, 186:10, 187:15, 189:8, 189:10, 189:12, 191:4, 191:11, 192:14, 195:8, 198:5, 200:7, 204:21, 204:23, 207:11, 208:13, 210:4, 210:15, 210:20, 211:13, 211:17, 215:23, 216:8, 216:15, 217:2, 217:5, 217:7, 217:14, 218:2, 219:6, 219:19, 219:20, 220:15, 221:6, 221:10, 221:11, 221:19, 222:6, 222:8, 224:14, 225:25, 227:8, 228:3, 228:19, 230:7, 231:23, 233:25, 234:7, 235:5, 236:8, 237:16, 237:18, 238:8, 240:13, 242:21, 242:25, 243:18, 243:21, 246:19, 246:24, 247:3, 247:12</p> <p>DEA's [24] - 17:21, 57:11, 57:17, 58:16, 79:3, 86:16, 90:1, 90:2, 90:14, 92:4, 94:1, 152:1, 153:19, 154:1, 155:6, 157:19, 173:8,</p>	<p>175:17, 193:10, 194:9, 196:3, 222:17, 233:19, 245:20</p> <p>deal [1] - 8:21</p> <p>dealing [1] - 229:23</p> <p>dealt [2] - 88:18, 127:1</p> <p>debate [2] - 53:8, 112:6</p> <p>December [14] - 9:4, 9:7, 9:9, 48:13, 48:18, 77:18, 78:5, 98:25, 142:21, 144:13, 232:18, 232:22, 232:23</p> <p>decide [3] - 28:17, 167:2, 167:15</p> <p>decided [3] - 123:18, 202:3, 202:4</p> <p>decides [2] - 119:21</p> <p>deciding [1] - 29:12</p> <p>decision [18] - 41:1, 42:4, 86:7, 89:10, 140:19, 148:10, 149:12, 149:15, 149:17, 149:19, 149:22, 150:21, 151:7, 151:9, 151:19, 152:8, 226:4</p> <p>decisions [4] - 129:18, 149:25, 150:5, 150:23</p> <p>deck [1] - 194:18</p> <p>declaration [6] - 91:25, 92:2, 92:3, 92:8, 93:16, 94:9</p> <p>decrease [1] - 202:21</p> <p>decreased [1] - 202:14</p> <p>deemed [2] - 111:10, 111:21</p> <p>deep [1] - 174:11</p> <p>Defendant [4] - 4:10, 5:2, 5:7, 6:2</p> <p>defendant [14] - 9:12, 9:15, 12:21, 30:20, 45:2, 59:14, 77:25, 94:25, 104:21, 109:6, 110:7, 182:11, 195:1, 215:21</p> <p>Defendants [3] - 1:8, 1:14, 250:7</p> <p>defendants [92] - 7:23, 26:8, 26:17, 26:22, 27:4, 31:3, 43:1, 45:1, 45:12, 45:13, 52:14, 52:15, 52:16, 56:11, 58:22, 63:19, 74:8, 74:17,</p>
<p style="text-align: center;">D</p>				
<p>daily [6] - 243:17, 243:20, 243:24, 243:25, 244:23, 245:4</p> <p>dangerous [1] - 117:19</p> <p>darn [1] - 134:9</p> <p>data [77] - 13:13, 16:6, 39:17, 156:14, 156:15, 156:18, 156:21, 157:9, 157:14, 157:19, 157:20, 157:25, 158:5, 158:9, 158:10, 158:15, 158:17, 158:18, 158:19, 159:4, 159:19, 160:10, 160:17, 161:3, 161:6, 161:15, 162:15, 162:17, 162:18, 162:19, 162:21, 163:5, 163:9, 163:11, 163:22, 163:24, 164:3, 164:5,</p>				

<p>74:25, 75:17, 82:11, 82:15, 82:20, 82:24, 83:7, 83:12, 83:24, 84:1, 84:6, 84:11, 97:18, 97:19, 100:8, 100:19, 102:17, 103:11, 104:14, 105:2, 105:18, 105:25, 107:3, 107:14, 113:6, 113:21, 114:23, 122:13, 123:2, 125:25, 127:19, 131:18, 135:13, 137:18, 139:2, 146:16, 149:23, 156:19, 157:8, 158:21, 159:13, 161:3, 161:21, 162:15, 167:4, 167:9, 168:9, 168:19, 168:22, 169:4, 169:11, 170:10, 172:20, 180:23, 181:4, 181:9, 181:22, 182:2, 182:18, 183:1, 183:4, 183:5, 183:15, 183:23, 186:4, 194:15, 205:8, 205:20, 215:9, 215:15, 217:1, 217:4, 217:25, 218:3</p> <p>defendants' [12] - 45:20, 100:24, 123:4, 125:1, 126:5, 126:6, 176:13, 177:16, 177:20, 180:22, 181:2, 183:12</p> <p>Defense [6] - 220:4, 223:13, 226:9, 229:2, 231:22, 235:23</p> <p>defense [1] - 137:5</p> <p>deficiencies [2] - 63:23, 66:4</p> <p>define [2] - 70:13, 70:17</p> <p>defined [2] - 55:10, 71:11</p> <p>defines [1] - 172:16</p> <p>definitely [2] - 162:19, 171:13</p> <p>definition [2] - 48:5, 172:19</p> <p>defy [1] - 229:10</p> <p>deliberate [2] - 42:4, 49:16</p>	<p>deliberative [2] - 8:15, 120:22</p> <p>delivered [1] - 101:10</p> <p>delivery [1] - 140:22</p> <p>demonstrable [1] - 26:9</p> <p>demonstrative [3] - 164:13, 166:7, 167:18</p> <p>Demonstrative [2] - 171:25, 172:1</p> <p>Denver [2] - 47:17, 47:18</p> <p>Department [6] - 42:19, 165:9, 165:18, 169:3, 175:15</p> <p>department [1] - 206:5</p> <p>deploy [2] - 22:17, 23:11</p> <p>deployed [3] - 23:14, 23:15</p> <p>deposed [4] - 127:23, 213:7, 237:21, 238:3</p> <p>deposition [26] - 55:24, 56:4, 73:24, 74:1, 75:4, 76:14, 76:20, 122:24, 123:11, 134:3, 134:11, 134:13, 134:16, 134:20, 135:3, 135:4, 135:5, 135:6, 135:13, 136:13, 136:16, 165:23, 167:8, 195:16, 203:23, 238:17</p> <p>depositions [1] - 128:4</p> <p>deputy [5] - 78:18, 81:22, 89:6, 89:10, 198:22</p> <p>Deputy [27] - 29:21, 29:23, 30:10, 30:18, 30:23, 31:6, 32:11, 57:14, 59:21, 61:17, 72:7, 102:15, 148:22, 149:6, 156:16, 156:17, 160:4, 162:20, 180:20, 181:20, 183:13, 186:24, 195:9, 198:6, 198:21, 204:17, 205:7</p> <p>describe [1] - 172:25</p> <p>described [10] - 60:23, 67:10, 69:18, 81:7, 89:23, 90:5, 90:16, 95:16, 165:7, 215:16</p>	<p>describes [1] - 92:3</p> <p>design [3] - 45:16, 45:19, 182:2</p> <p>designate [1] - 134:17</p> <p>designated [7] - 123:1, 123:2, 123:3, 134:15, 134:21, 135:3, 167:9</p> <p>designating [2] - 135:4, 135:5</p> <p>designation [3] - 135:2, 135:8, 137:8</p> <p>designations [9] - 122:24, 123:11, 134:3, 134:11, 134:13, 134:21, 134:25, 136:13, 136:17</p> <p>desk [1] - 30:17</p> <p>despite [1] - 36:23</p> <p>Despite [1] - 233:25</p> <p>destined [1] - 141:1</p> <p>detail [2] - 15:1, 248:19</p> <p>detailed [2] - 71:24, 170:25</p> <p>details [12] - 91:7, 92:4, 93:5, 110:22, 114:12, 167:23, 232:3, 242:18, 242:23, 243:6, 244:8, 244:15</p> <p>detect [7] - 48:16, 48:25, 49:3, 69:14, 81:9, 89:21, 166:15</p> <p>detecting [1] - 160:20</p> <p>determination [6] - 13:20, 29:22, 30:24, 87:15, 157:3, 198:13</p> <p>determine [11] - 9:4, 29:16, 61:16, 95:24, 110:22, 142:14, 167:5, 178:14, 180:21, 234:9, 234:18</p> <p>determined [1] - 193:14</p> <p>determining [1] - 141:11</p> <p>detriment [1] - 141:3</p> <p>Detroit [1] - 247:10</p> <p>develop [2] - 235:5, 235:7</p> <p>development [4] - 197:17, 197:24, 199:23, 200:3</p> <p>dial [1] - 137:15</p> <p>difference [1] - 46:12</p> <p>different [26] - 24:14, 25:21, 25:22, 29:5,</p>	<p>54:4, 55:19, 107:6, 110:6, 118:19, 128:2, 132:24, 140:12, 145:24, 146:13, 158:18, 163:21, 176:5, 176:20, 197:3, 197:14, 201:15, 207:20, 242:5</p> <p>difficult [5] - 41:11, 74:12, 171:6, 171:7, 171:15</p> <p>diligence [21] - 84:9, 89:17, 89:19, 94:16, 94:20, 95:5, 95:12, 95:15, 95:20, 95:21, 118:7, 118:9, 151:8, 173:23, 174:1, 177:23, 186:20, 245:18, 246:2, 246:4</p> <p>direct [16] - 14:1, 16:4, 60:11, 72:24, 92:16, 100:5, 123:25, 126:2, 135:20, 140:3, 192:10, 203:6, 203:11, 218:23, 219:7, 232:4</p> <p>directed [5] - 13:19, 100:6, 143:13, 165:9, 206:14</p> <p>directing [1] - 41:21</p> <p>direction [7] - 13:1, 37:11, 57:16, 141:19, 145:4, 145:14, 211:5</p> <p>directions [1] - 132:2</p> <p>directly [2] - 101:2, 219:25</p> <p>Director [2] - 156:16, 188:17</p> <p>directs [1] - 214:1</p> <p>dis [1] - 78:23</p> <p>disagreeing [1] - 137:2</p> <p>disapprove [2] - 140:13, 140:16</p> <p>disclose [8] - 8:7, 8:12, 42:3, 49:19, 106:8, 165:25, 166:4, 175:16</p> <p>disclosing [1] - 49:24</p> <p>discovered [2] - 111:22, 145:9</p> <p>discrete [1] - 133:7</p> <p>discretion [1] - 157:2</p> <p>discuss [11] - 12:10, 58:2, 99:12, 99:14, 143:2, 153:1, 165:9, 181:23, 243:12, 243:16, 244:2</p>	<p>discussed [7] - 8:9, 12:11, 55:24, 88:15, 102:12, 137:10, 172:19</p> <p>discusses [2] - 58:3, 232:12</p> <p>discussing [3] - 12:12, 26:15, 231:12</p> <p>discussion [1] - 139:1</p> <p>discussions [3] - 91:18, 236:3, 240:9</p> <p>dispensation [1] - 75:7</p> <p>dispense [1] - 228:14</p> <p>dispensed [3] - 24:19, 190:19, 229:9</p> <p>dispenses [1] - 229:11</p> <p>dispensing [4] - 163:16, 163:18, 163:19, 165:7</p> <p>disposal [1] - 199:7</p> <p>disproportionate [1] - 120:13</p> <p>distinction [1] - 202:8</p> <p>distribute [2] - 9:13, 117:5</p> <p>distributed [6] - 25:5, 38:16, 45:17, 148:15, 191:12, 220:19</p> <p>distributing [5] - 29:8, 45:6, 163:18, 163:20, 228:25</p> <p>Distribution [16] - 15:22, 37:15, 37:19, 38:1, 39:7, 39:8, 39:13, 46:2, 46:10, 47:4, 47:6, 47:17, 47:23, 61:13, 97:10, 97:13</p> <p>distribution [48] - 38:4, 39:21, 43:21, 43:22, 43:23, 43:25, 44:1, 44:3, 44:25, 45:15, 46:4, 48:13, 58:17, 61:12, 62:6, 69:10, 77:14, 78:23, 80:22, 81:2, 81:12, 81:13, 90:2, 90:7, 90:18, 110:7, 110:8, 148:16, 176:13, 177:16, 180:22, 181:3, 181:11, 204:8, 210:6, 212:25, 213:14, 220:11, 220:12, 231:11, 234:11, 234:20, 239:21, 239:25, 243:21,</p>
--	---	---	--	---

<p>244:8, 244:9, 244:16 distributions [1] - 118:17 distributor [57] - 7:21, 13:21, 14:8, 15:10, 28:6, 28:7, 28:19, 29:7, 30:6, 45:11, 58:20, 60:19, 63:9, 82:11, 102:16, 103:12, 103:13, 105:13, 106:13, 109:18, 110:16, 110:19, 111:6, 114:4, 114:15, 116:22, 116:23, 117:20, 118:6, 118:23, 118:24, 119:6, 119:9, 119:13, 120:6, 120:16, 126:22, 139:24, 151:22, 152:4, 161:7, 163:20, 173:22, 175:25, 180:8, 180:13, 180:22, 181:7, 182:22, 182:23, 212:7, 212:9, 212:16, 226:22, 227:3, 230:3 distributor's [5] - 118:11, 173:10, 178:1, 179:5, 182:11 Distributors [1] - 84:23 distributors [59] - 25:17, 57:12, 57:17, 97:16, 106:16, 115:18, 115:20, 117:3, 117:7, 117:13, 117:15, 118:16, 120:19, 121:20, 144:25, 148:16, 151:4, 152:25, 153:16, 156:18, 158:17, 158:19, 158:25, 159:1, 159:16, 160:10, 160:18, 161:7, 161:15, 162:2, 162:3, 162:4, 162:21, 162:25, 163:2, 163:23, 164:4, 164:15, 164:16, 166:15, 166:19, 168:8, 168:18, 168:21, 174:6, 174:16, 175:14, 175:23, 176:24, 205:8, 207:14, 211:22,</p>	<p>212:21, 213:3, 214:13, 217:11, 217:13, 218:17, 235:2 distributors' [1] - 169:14 DISTRICT [3] - 1:1, 1:1, 1:17 District [4] - 7:2, 7:3, 91:22, 188:16 diversion [57] - 21:22, 21:24, 21:25, 25:18, 27:21, 30:8, 31:11, 47:7, 47:18, 48:12, 62:14, 62:24, 69:8, 70:24, 71:1, 71:14, 80:21, 117:14, 117:17, 117:21, 118:24, 119:6, 120:4, 139:12, 139:15, 141:13, 141:17, 151:5, 151:9, 152:10, 156:15, 160:20, 162:23, 166:16, 167:6, 167:10, 168:10, 169:12, 169:15, 171:5, 177:9, 177:21, 180:24, 181:5, 190:21, 191:18, 191:23, 196:4, 198:22, 199:1, 200:7, 204:5, 211:12, 211:13, 213:1, 238:12, 240:13 Diversions [12] - 139:10, 139:11, 139:23, 192:12, 204:19, 210:21, 211:8, 211:10, 211:12, 211:18, 211:23, 214:19 diversions [1] - 203:20 diverted [9] - 89:18, 104:16, 105:4, 105:20, 106:1, 106:17, 107:7, 118:8, 141:9 diverters [1] - 103:16 division [2] - 91:9, 247:10 Division [3] - 23:18, 176:21, 188:17 Docket [1] - 73:25 docket [1] - 75:3 doctor [8] - 21:1, 21:9, 21:12, 28:18, 29:10,</p>	<p>30:5, 119:12 doctor's [2] - 186:16 doctor-patient [1] - 21:12 doctors [4] - 22:8, 186:11, 186:15, 202:17 document [95] - 10:8, 11:5, 11:15, 14:1, 14:24, 15:2, 30:24, 32:13, 32:23, 34:25, 38:4, 44:10, 46:24, 47:3, 68:8, 68:10, 73:11, 74:11, 76:4, 76:8, 77:8, 77:10, 77:20, 78:7, 78:9, 80:3, 84:21, 85:15, 86:2, 86:4, 86:12, 86:22, 87:1, 87:5, 87:20, 88:4, 88:8, 88:16, 91:15, 91:17, 91:19, 93:10, 94:5, 96:10, 96:24, 98:1, 98:4, 98:7, 98:11, 98:18, 98:19, 101:10, 109:3, 109:14, 116:19, 116:21, 120:18, 139:6, 139:7, 139:20, 142:2, 142:14, 142:15, 143:2, 143:16, 143:20, 149:4, 150:7, 153:6, 154:13, 154:17, 154:22, 180:14, 187:9, 188:22, 188:25, 189:2, 189:15, 190:7, 192:11, 193:3, 218:23, 219:11, 219:12, 224:23, 233:3, 233:6, 233:12, 236:23, 240:20, 241:3, 241:12, 242:21, 248:4 documents [8] - 74:8, 75:18, 85:20, 96:6, 128:5, 147:21, 189:25, 226:7 DOJ [5] - 34:14, 187:18, 187:20, 187:22, 189:10 Donald [2] - 237:8, 248:6 done [21] - 25:21, 28:7, 44:17, 58:3, 94:14, 100:12, 123:19, 124:6,</p>	<p>132:7, 134:21, 153:10, 164:20, 167:13, 168:6, 181:15, 185:2, 194:24, 207:11, 214:6, 229:15, 248:3 dosage [8] - 16:14, 16:16, 16:19, 60:21, 70:25, 196:25, 229:10, 239:18 dosages [1] - 165:2 dose [1] - 25:10 doses [2] - 18:3, 25:14 doubt [3] - 20:11, 56:11, 128:18 Douglas [1] - 4:17 down [41] - 21:6, 22:2, 23:12, 23:16, 24:4, 24:23, 25:15, 67:22, 86:23, 119:14, 123:20, 125:5, 126:13, 129:17, 130:13, 131:4, 132:18, 133:18, 133:19, 135:19, 136:4, 141:5, 202:5, 202:15, 202:16, 202:22, 203:20, 215:13, 220:23, 227:10, 228:18, 228:22, 228:24, 229:16, 234:3, 235:1, 239:6, 243:11, 243:14, 247:11 down-schedule [1] - 202:5 downstream [10] - 9:5, 9:14, 13:15, 71:25, 79:10, 84:8, 95:25, 167:24, 190:20, 239:18 dozen [2] - 215:16, 215:19 DPM [1] - 91:10 Dr [6] - 98:15, 123:18, 126:2, 126:3, 128:1, 130:8 dramatically [2] - 202:14, 202:21 draw [1] - 120:8 drink [1] - 35:21 Drive [1] - 6:15 driver's [2] - 119:17, 119:18 drop [1] - 123:18 dropped [1] - 123:15 dropping [1] - 136:4 drug [39] - 21:7, 24:25, 94:16, 95:6, 95:10,</p>	<p>117:18, 190:24, 196:24, 197:1, 197:7, 197:22, 197:24, 199:13, 200:5, 200:11, 200:14, 200:17, 200:18, 200:21, 201:1, 201:9, 201:19, 201:23, 201:25, 202:1, 202:15, 203:1, 203:2, 203:7, 203:12, 203:16, 203:20, 203:21, 204:6, 204:11, 204:12, 204:13 Drug [6] - 6:2, 68:13, 187:16, 220:10, 237:6, 250:7 DRUG [2] - 1:7, 1:13 drug-seeking [2] - 21:7, 204:11 drugs [34] - 17:9, 18:10, 18:20, 19:20, 20:8, 22:13, 24:7, 25:5, 25:7, 26:2, 67:12, 121:8, 148:15, 159:7, 160:11, 161:4, 161:22, 162:15, 162:16, 167:24, 167:25, 179:24, 179:25, 191:7, 194:12, 199:16, 200:25, 203:6, 203:20, 204:6, 204:9, 204:25, 221:1 due [28] - 84:9, 89:16, 89:19, 94:16, 94:20, 95:5, 95:12, 95:15, 95:20, 95:21, 118:6, 118:9, 119:7, 151:8, 173:23, 174:1, 175:1, 175:4, 177:23, 186:20, 229:13, 229:14, 229:23, 241:4, 241:7, 245:18, 246:2, 246:4 Due [2] - 95:20, 229:14 during [66] - 11:5, 11:19, 23:25, 25:9, 26:3, 28:24, 29:13, 29:24, 30:9, 30:19, 31:3, 31:18, 33:22, 51:2, 54:10, 54:17, 57:10, 57:14, 67:13, 72:7, 72:18, 94:15, 97:6, 113:20,</p>
--	--	---	--	---

<p>113:23, 114:4, 114:19, 115:16, 126:7, 139:14, 139:16, 154:15, 157:8, 167:20, 168:6, 168:7, 171:4, 172:21, 174:7, 175:17, 177:2, 177:14, 177:15, 177:19, 179:1, 180:20, 181:3, 181:18, 181:20, 183:1, 183:5, 183:13, 184:1, 186:1, 195:8, 195:9, 196:23, 199:3, 199:15, 212:7, 215:23, 216:18, 218:14, 228:1, 239:9 During [2] - 114:19, 114:25 duties [1] - 186:24 dynamics [1] - 201:15</p>	<p>193:5, 194:19 ELIZABETH [1] - 6:14 elsewhere [2] - 46:2, 91:1 email [1] - 192:11 embrace [1] - 26:16 embraces [1] - 11:20 emerged [1] - 21:25 employees [1] - 248:10 Encino [1] - 3:18 encompassed [1] - 88:21 encourage [1] - 129:14 encouraging [1] - 129:17 end [13] - 27:12, 87:4, 124:11, 124:12, 127:21, 127:22, 128:7, 133:18, 133:23, 134:17, 134:18, 176:8, 201:3 Enforcement [6] - 68:13, 161:14, 187:16, 188:18, 220:10, 237:6 enforcement [46] - 8:16, 41:21, 42:3, 43:1, 43:3, 49:16, 72:12, 72:16, 74:2, 74:17, 74:20, 74:22, 75:25, 76:21, 78:16, 83:23, 106:7, 115:14, 120:23, 133:14, 133:15, 133:16, 137:15, 137:16, 137:18, 137:20, 150:5, 156:14, 158:5, 165:10, 165:24, 166:3, 166:13, 167:22, 170:10, 170:15, 174:11, 174:18, 181:19, 193:11, 193:15, 195:23, 196:3, 207:23, 208:10, 208:11 enforcing [1] - 206:20 engaged [1] - 36:25 engaging [2] - 36:25, 75:14 enhanced [1] - 96:20 enormous [1] - 117:21 ensure [8] - 58:4, 89:17, 197:7, 197:11, 199:10, 200:11, 201:8, 229:15</p>	<p>entered [3] - 82:25, 83:7, 96:2 entire [7] - 11:20, 26:16, 33:6, 39:23, 87:5, 88:21, 210:5 entirely [1] - 137:9 entities [1] - 210:11 entitled [1] - 127:4 entity [2] - 100:24, 119:12 entry [1] - 75:3 ENU [1] - 4:12 epidemic [1] - 200:6 epidemiologist [1] - 133:12 epidemiologists [4] - 130:6, 131:1, 132:15, 132:21 equivalent [1] - 125:18 error [1] - 157:21 errors [5] - 157:17, 157:19, 157:20, 157:23 especially [2] - 135:11, 162:6 essentially [1] - 125:22 establish [3] - 196:22, 196:24, 197:4 established [5] - 71:14, 88:4, 196:23, 200:17, 247:14 estimate [2] - 123:24, 196:18 et [6] - 1:7, 1:13, 91:8, 165:2, 250:6, 250:7 evaluate [2] - 123:16, 152:7 evaluating [1] - 174:4 event [2] - 54:9, 58:10 events [1] - 152:18 eventually [1] - 198:15 evidence [14] - 14:2, 44:24, 71:14, 126:25, 127:5, 129:15, 150:22, 164:12, 219:13, 223:12, 225:7, 226:8, 228:21, 229:16 Evidence [1] - 127:4 evidentiary [1] - 126:25 evidently [1] - 137:19 exact [2] - 59:1, 144:2 exactly [5] - 11:5, 26:25, 112:6, 125:19, 227:17 exam [1] - 218:24</p>	<p>EXAMINATION [1] - 209:22 examination [8] - 21:18, 22:12, 33:22, 125:1, 164:18, 219:7, 232:4, 238:20 examinations [2] - 125:6, 132:6 examine [2] - 41:15, 56:11 examining [1] - 135:23 example [12] - 108:3, 108:16, 131:2, 132:16, 133:12, 133:13, 145:18, 157:21, 191:11, 194:22, 201:21, 201:22 examples [2] - 109:16, 190:21 exceeds [1] - 75:2 Excel [1] - 124:13 except [2] - 20:14, 78:19 exception [3] - 34:14, 94:24, 140:20 excess [1] - 191:12 Excessive [2] - 109:15, 145:10 excessive [19] - 103:17, 103:18, 103:20, 103:23, 104:3, 104:12, 109:16, 112:2, 112:13, 113:7, 113:21, 114:23, 115:1, 213:22, 214:18, 214:21, 214:24, 234:9, 234:18 excluded [1] - 86:12 excuse [3] - 60:3, 151:15, 170:12 excuses [1] - 155:20 executed [2] - 181:16, 206:2 executive [3] - 97:23, 99:5, 99:6 exercise [4] - 118:6, 118:9, 119:7, 200:10 exhibit [8] - 72:25, 87:18, 108:7, 108:24, 116:16, 194:2, 194:4, 195:4 exhibits [2] - 74:25, 75:1 exist [1] - 186:21 Existed [1] - 127:4 expect [3] - 83:16,</p>	<p>131:18, 146:18 expectation [1] - 151:3 expected [1] - 39:19 expecting [1] - 131:21 expense [1] - 203:1 experience [13] - 24:19, 104:5, 168:9, 169:10, 178:20, 184:18, 185:9, 193:11, 195:22, 203:19, 203:25, 204:4, 204:5 experiencing [1] - 126:9 expert [25] - 53:2, 53:5, 53:11, 53:19, 55:4, 56:3, 98:20, 131:14, 133:6, 137:9, 155:12, 164:2, 166:24, 178:17, 191:20, 193:6, 193:10, 194:19, 195:13, 195:15, 195:17, 196:8, 207:18, 208:4 Expert [1] - 203:22 experts [6] - 127:25, 128:1, 129:21, 131:16, 135:20, 195:14 explain [17] - 17:21, 20:20, 30:2, 31:17, 37:15, 52:3, 52:4, 52:6, 53:2, 75:21, 145:4, 171:8, 175:22, 194:9, 196:16, 229:20, 237:13 explained [4] - 31:1, 37:12, 43:3, 208:22 explaining [1] - 175:23 explanation [8] - 16:25, 17:6, 17:8, 37:9, 111:10, 111:20, 130:1, 236:5 export [3] - 197:18, 197:24, 199:24 Express [3] - 23:25, 24:4, 24:8 express [5] - 48:24, 58:15, 61:20, 100:23, 151:3 expressed [2] - 83:15, 83:20 expressing [1] - 141:2 expressly [1] - 74:25 extended [4] - 141:6, 141:7, 178:25, 179:3</p>
E				
<p>E-commerce [2] - 11:3, 16:6 e-mail [1] - 175:23 early [3] - 34:7, 122:9, 215:6 East [3] - 3:5, 3:12, 4:18 economist [1] - 130:7 education [1] - 208:1 educational [2] - 220:19, 248:9 effect [3] - 41:1, 49:2, 223:16 effective [11] - 30:8, 46:9, 47:5, 47:17, 118:23, 119:5, 152:10, 177:21, 180:23, 181:1, 181:4 effectively [1] - 178:15 efficiency [1] - 34:5 efficiently [1] - 138:6 effort [2] - 133:18, 138:5 eight [2] - 36:14, 247:20 Eighth [1] - 3:10 either [10] - 21:3, 24:6, 24:20, 37:22, 74:3, 126:12, 199:7, 200:25, 201:6 electronically [1] - 235:3 element [1] - 188:12 elicit [3] - 19:25,</p>				

<p>extension [1] - 132:19</p> <p>extensively [2] - 74:16, 75:24</p> <p>extent [11] - 11:22, 17:6, 49:11, 49:14, 88:11, 117:17, 146:6, 147:6, 147:8, 167:2, 167:15</p> <p>external [1] - 98:7</p> <p>extra [4] - 43:8, 128:12, 130:11</p> <p>extraordinary [1] - 36:23</p> <p>extremely [1] - 221:11</p> <p>eye [1] - 119:1</p> <p>eyes [1] - 70:5</p>	<p>241:14</p> <p>factual [2] - 20:1, 56:7</p> <p>failed [7] - 47:5, 47:16, 89:16, 89:20, 180:23, 180:25, 181:4</p> <p>failings [1] - 90:19</p> <p>Failure [1] - 118:9</p> <p>failure [20] - 18:21, 19:4, 19:19, 19:21, 20:8, 39:11, 39:23, 46:9, 48:11, 48:16, 58:11, 64:14, 69:7, 69:14, 80:20, 81:8, 88:20, 89:19, 90:25</p> <p>failures [5] - 79:11, 90:5, 90:16, 95:15, 95:16</p> <p>fair [2] - 65:11, 160:8</p> <p>falls [1] - 34:21</p> <p>familiar [13] - 44:14, 59:4, 64:5, 64:7, 70:1, 77:2, 77:20, 80:11, 82:15, 98:24, 152:20, 153:6, 172:2</p> <p>family [3] - 190:22, 191:2, 191:9</p> <p>far [5] - 49:18, 115:5, 183:25, 185:4, 207:8</p> <p>FARRELL [6] - 2:3, 34:18, 55:21, 55:23, 87:17, 165:16</p> <p>Farrell [8] - 2:4, 2:15, 34:17, 54:8, 55:18, 87:16, 124:6, 165:15</p> <p>faster [1] - 135:18</p> <p>fault [1] - 126:18</p> <p>FCRR [1] - 6:18</p> <p>fear [2] - 54:8, 125:5</p> <p>February [2] - 142:23, 143:23</p> <p>Federal [7] - 91:22, 149:21, 149:24, 150:10, 179:21, 179:22</p> <p>federal [2] - 179:21, 210:4</p> <p>feedback [3] - 113:6, 114:23, 182:1</p> <p>feelings [1] - 115:7</p> <p>feet [1] - 42:23</p> <p>felt [4] - 30:11, 54:24, 81:19, 144:4</p> <p>few [11] - 43:21, 115:10, 128:6, 177:13, 178:13, 184:12, 186:22, 220:14, 232:2, 239:6</p> <p>Field [7] - 23:18, 140:8, 140:9,</p>	<p>140:13, 140:21, 176:21</p> <p>field [4] - 140:16, 153:1, 211:4, 247:10</p> <p>figure [3] - 163:19, 185:2, 186:11</p> <p>figured [1] - 131:21</p> <p>file [6] - 33:13, 35:3, 35:14, 58:21, 58:24, 118:16</p> <p>filed [3] - 37:25, 59:2, 59:5</p> <p>files [3] - 173:23, 174:1, 177:23</p> <p>filing [3] - 33:6, 33:7, 145:10</p> <p>fill [3] - 20:24, 34:16, 141:1</p> <p>filled [2] - 25:4, 120:14</p> <p>filling [2] - 118:7, 119:8</p> <p>fills [2] - 21:6, 21:16</p> <p>final [6] - 29:9, 137:14, 148:10, 148:23, 150:7, 150:9</p> <p>findings [7] - 32:24, 88:8, 90:2, 180:7, 180:13, 181:10, 181:18</p> <p>fine [12] - 14:25, 36:3, 36:4, 36:7, 38:21, 65:22, 107:6, 124:18, 200:25, 209:8, 209:10, 226:2</p> <p>finish [8] - 102:14, 119:3, 123:14, 125:4, 133:23, 138:2, 138:5, 139:1</p> <p>finished [2] - 15:8, 180:6</p> <p>Firm [2] - 3:4, 3:7</p> <p>firm [1] - 33:20</p> <p>first [34] - 9:21, 14:4, 16:14, 52:5, 64:23, 77:2, 77:3, 116:7, 116:15, 116:22, 118:14, 121:13, 121:15, 126:22, 128:19, 129:4, 130:16, 140:2, 140:7, 140:14, 162:14, 181:1, 190:5, 192:10, 193:3, 197:21, 215:5, 224:25, 226:18, 227:24, 234:24, 237:1, 237:2, 244:1</p> <p>fit [1] - 221:4</p> <p>fits [1] - 42:17</p>	<p>five [16] - 24:6, 108:24, 126:1, 133:6, 158:3, 170:5, 176:17, 177:4, 202:11, 210:24, 232:5, 232:14, 232:19, 232:23, 235:11, 247:11</p> <p>fixed [1] - 239:23</p> <p>FL [1] - 2:14</p> <p>flag [4] - 121:5, 121:11, 161:1, 217:14</p> <p>flags [4] - 14:20, 14:21, 151:9</p> <p>Flaherty [1] - 5:14</p> <p>FLAHIVE [1] - 5:10</p> <p>flawed [1] - 158:10</p> <p>flip [3] - 80:25, 81:5, 248:8</p> <p>Floor [1] - 3:5</p> <p>floor [1] - 179:24</p> <p>floored [1] - 17:14</p> <p>Florida [16] - 11:16, 20:18, 20:19, 22:15, 23:14, 24:5, 25:15, 36:22, 77:15, 86:6, 88:17, 95:9, 215:10, 216:23, 216:24, 220:12</p> <p>flow [1] - 9:5</p> <p>fluctuations [1] - 247:13</p> <p>fly [1] - 74:13</p> <p>focus [4] - 43:24, 52:14, 211:20, 211:21</p> <p>focused [3] - 20:15, 115:13, 215:9</p> <p>focusing [2] - 27:9, 27:19</p> <p>follow [6] - 7:17, 82:16, 198:1, 244:3, 244:10, 244:16</p> <p>followed [1] - 219:22</p> <p>following [10] - 16:8, 48:8, 48:21, 75:13, 80:18, 88:5, 143:6, 182:23, 238:11</p> <p>follows [4] - 7:5, 16:12, 67:25, 184:9</p> <p>Footnote [1] - 151:12</p> <p>FOR [1] - 1:1</p> <p>forbidden [1] - 50:2</p> <p>force [1] - 130:12</p> <p>Force [7] - 211:13, 246:20, 246:23, 247:3, 247:4, 247:7, 247:9</p> <p>forces [1] - 134:19</p>	<p>foregoing [1] - 250:4</p> <p>forget [1] - 128:19</p> <p>forgive [3] - 64:22, 66:8, 106:14</p> <p>forgot [2] - 114:20</p> <p>form [3] - 195:10, 206:11, 211:14</p> <p>formal [1] - 147:17</p> <p>format [2] - 114:7, 150:10</p> <p>formula [1] - 145:16</p> <p>formulations [1] - 199:17</p> <p>forth [5] - 32:23, 69:15, 88:8, 141:4, 166:22</p> <p>forward [3] - 43:18, 56:1, 138:16</p> <p>Foundation [1] - 103:2</p> <p>foundation [59] - 18:25, 27:25, 28:1, 38:3, 38:6, 38:24, 50:16, 50:24, 51:12, 51:14, 52:5, 55:2, 62:3, 62:9, 64:2, 66:11, 66:17, 69:23, 70:12, 71:4, 82:2, 83:2, 83:4, 86:21, 87:20, 90:8, 95:18, 98:17, 98:18, 98:22, 102:6, 104:17, 104:22, 105:9, 105:21, 106:12, 106:17, 106:21, 109:21, 110:25, 111:12, 112:9, 121:21, 145:25, 155:10, 155:11, 155:23, 161:5, 161:10, 162:2, 162:8, 163:1, 164:7, 164:11, 166:25, 178:17, 185:12, 188:12, 194:25</p> <p>founder [1] - 157:20</p> <p>founders [1] - 157:19</p> <p>four [11] - 18:1, 24:5, 30:23, 47:24, 88:16, 90:17, 130:16, 131:12, 178:13, 236:17, 243:11</p> <p>Four [1] - 243:14</p> <p>frame [4] - 113:9, 113:10, 113:17, 214:14</p> <p>framework [2] - 132:10, 157:5</p> <p>frankly [4] - 129:25, 130:14, 166:17,</p>
F				
<p>F.R.E [2] - 188:8, 188:19</p> <p>F.Supp [1] - 188:15</p> <p>Faber [1] - 7:2</p> <p>FABER [1] - 1:17</p> <p>face [2] - 11:15, 98:6</p> <p>facilitate [1] - 117:21</p> <p>facilitating [1] - 22:3</p> <p>facilitation [3] - 20:23, 21:4, 21:15</p> <p>facilities [7] - 18:23, 48:14, 69:10, 80:23, 177:7, 181:17, 231:17</p> <p>Facility [1] - 78:12</p> <p>facility [20] - 18:22, 37:18, 37:19, 37:20, 40:6, 47:7, 47:18, 67:14, 69:10, 73:18, 77:4, 77:25, 86:6, 94:14, 142:6, 177:12, 178:10, 178:24, 181:14, 201:11</p> <p>fact [26] - 14:11, 17:19, 17:20, 18:15, 19:23, 38:7, 43:20, 55:9, 56:5, 56:6, 56:18, 64:8, 72:11, 72:16, 114:5, 118:25, 119:9, 119:15, 131:13, 138:19, 164:3, 166:14, 208:24, 240:11, 244:15</p> <p>factor [4] - 134:14, 247:13, 247:15, 247:20</p> <p>facts [7] - 45:8, 56:2, 126:24, 164:12, 206:12, 206:15,</p>				

<p>203:5 FRE ^[1] - 34:25 Fred's ^[1] - 42:23 free ^[2] - 207:23, 208:2 frequencies ^[1] - 177:1 frequency ^[1] - 177:2 frequent ^[1] - 168:7 frequently ^[3] - 157:9, 168:5, 191:6 Friday ^[5] - 125:4, 125:12, 136:6, 136:20, 138:7 friends ^[5] - 122:25, 127:2, 190:23, 191:2, 191:8 front ^[14] - 40:15, 85:22, 96:7, 96:25, 107:24, 136:22, 141:24, 221:16, 226:4, 226:7, 231:22, 233:8, 236:18, 240:21 full ^[15] - 131:19, 131:22, 137:7, 140:3, 145:14, 174:6, 176:25, 178:9, 179:18, 190:17, 222:16, 223:2, 234:8, 244:1, 246:2 Full ^[1] - 64:9 full-time ^[1] - 178:9 FULLER ^[1] - 2:15 Fuller ^[2] - 2:4, 2:15 fully ^[2] - 131:21, 172:24 function ^[1] - 193:15 funky ^[1] - 221:19 Furthermore ^[1] - 89:20</p>	<p>122:19, 162:1, 162:25, 169:8, 170:4, 182:4, 198:1 generate ^[1] - 243:12 generated ^[1] - 243:13 generic ^[8] - 18:10, 18:13, 18:18, 18:20, 19:20, 20:8, 40:5 generics ^[1] - 239:11 generous ^[1] - 34:20 gentleman ^[1] - 236:15 gentlemen ^[3] - 17:11, 236:17, 237:10 geographic ^[6] - 11:14, 11:21, 76:9, 88:16, 88:18, 88:23 geographical ^[1] - 26:18 Georgia ^[2] - 24:9 get-go ^[1] - 129:9 Gina ^[2] - 16:1, 151:13 given ^[23] - 24:4, 34:14, 49:21, 103:24, 111:21, 117:17, 118:22, 127:13, 127:17, 128:3, 129:20, 131:11, 141:19, 154:25, 171:19, 182:16, 199:22, 216:1, 216:2, 216:6, 216:7, 229:6 glass ^[1] - 136:4 goal ^[1] - 31:6 governed ^[2] - 157:5, 196:20 government ^[2] - 33:10, 207:15 governmental ^[1] - 33:10 great ^[1] - 248:24 GRETCHEN ^[1] - 6:7 grew ^[1] - 200:7 ground ^[5] - 20:14, 26:12, 57:4, 62:4, 100:2 grounds ^[2] - 151:16, 209:5 group ^[9] - 22:7, 91:10, 175:24, 198:9, 207:23, 207:24, 207:25, 211:15 groups ^[3] - 23:21, 207:20, 207:21 growing ^[1] - 234:2 guarantee ^[1] - 119:13 guess ^[12] - 17:12, 45:2, 62:3, 100:11,</p>	<p>129:3, 132:25, 137:25, 148:13, 164:6, 164:24, 237:12 guidance ^[41] - 12:18, 39:19, 57:11, 57:13, 57:15, 57:17, 58:4, 94:25, 114:11, 114:12, 114:14, 115:15, 115:18, 117:24, 121:17, 121:19, 139:1, 145:4, 145:24, 146:7, 147:4, 147:7, 147:11, 147:16, 150:1, 152:3, 152:11, 152:12, 152:17, 153:16, 156:7, 156:9, 172:19, 173:2, 173:5, 173:14, 183:22, 186:10, 215:1, 215:23, 240:13 guy ^[1] - 17:10</p>	<p>100:16 head ^[2] - 210:21, 211:23 headed ^[1] - 25:2 heading ^[2] - 246:15, 246:18 headquarters ^[3] - 45:21, 45:23, 91:11 Headquarters ^[2] - 12:6, 13:22 Health ^[17] - 4:11, 5:2, 73:18, 74:2, 74:22, 76:21, 77:13, 78:2, 78:12, 80:6, 84:22, 93:2, 142:5, 142:13, 143:4, 143:13, 163:9 health ^[4] - 30:1, 61:17, 141:3, 190:24 healthcare ^[2] - 184:15, 184:19 Healthcare ^[2] - 97:10, 97:13 hear ^[11] - 8:10, 10:18, 38:23, 40:21, 49:12, 55:22, 73:15, 122:9, 128:24, 201:16, 245:5 heard ^[8] - 23:25, 24:11, 130:25, 133:14, 137:19, 155:20, 211:7, 212:7 hearing ^[10] - 115:8, 125:13, 130:20, 149:9, 149:12, 154:4, 187:14, 187:19, 189:7, 189:11 hearsay ^[36] - 12:13, 12:16, 12:24, 40:9, 53:2, 54:21, 55:2, 56:23, 57:3, 57:18, 75:15, 83:2, 83:4, 83:10, 94:21, 94:24, 95:3, 99:24, 100:2, 100:7, 100:13, 100:19, 100:22, 101:3, 101:17, 102:7, 155:23, 188:3, 188:6, 193:3, 193:4, 223:15, 223:18, 238:18 heart ^[1] - 34:13 heavy ^[1] - 131:14 held ^[2] - 12:5, 151:21 help ^[9] - 43:7, 43:9, 127:7, 136:23, 151:13, 163:6, 171:13, 190:16, 200:25 helped ^[1] - 169:15</p>	<p>helpful ^[5] - 113:8, 113:22, 114:24, 130:2, 227:2 helps ^[2] - 240:23, 248:14 hemorrhaging ^[1] - 31:8 hereby ^[1] - 49:1 herein ^[1] - 89:23 heroin ^[4] - 193:13, 195:12, 195:24, 196:4 Hester ^[5] - 98:14, 129:1, 136:10, 137:3, 137:23 HESTER ^[10] - 5:9, 129:2, 131:20, 132:1, 133:11, 134:2, 134:8, 136:11, 137:24, 138:10 high ^[4] - 25:10, 124:12, 234:8, 234:17 highlight ^[2] - 134:2, 237:8 highlighted ^[3] - 227:25, 237:20, 238:3 highlighting ^[1] - 129:3 highlights ^[1] - 194:13 highly ^[1] - 166:8 Highway ^[2] - 24:11, 24:18 Hilliard ^[8] - 237:9, 239:9, 239:10, 239:15, 246:6, 246:8, 246:18, 247:11 himself ^[1] - 111:13 historical ^[1] - 166:24 history ^[2] - 34:7, 128:15 hit ^[1] - 30:17 home ^[1] - 136:22 Homeland ^[1] - 187:13 homework ^[1] - 123:20 honest ^[1] - 236:20 Honor ^[221] - 7:7, 8:3, 8:6, 8:20, 8:25, 10:4, 11:11, 11:25, 12:14, 12:17, 13:5, 14:10, 14:22, 19:1, 19:2, 19:7, 19:22, 20:2, 22:20, 22:25, 26:6, 26:11, 27:3, 27:13, 28:2, 32:1, 33:1, 33:4, 33:17, 33:23,</p>
H				
<p>habits ^[1] - 186:17 Haight ^[3] - 22:1, 215:14, 215:18 half ^[7] - 50:15, 50:16, 123:10, 131:7, 133:6, 219:16, 233:19 half-days ^[1] - 123:10 halt ^[1] - 141:12 handed ^[1] - 139:6 handle ^[2] - 8:21, 200:3 handled ^[1] - 185:24 hands ^[2] - 203:21, 204:6 handwriting ^[1] - 160:8 happy ^[3] - 54:16, 65:3, 115:5 hard ^[7] - 129:18, 132:4, 134:9, 138:2, 183:4, 183:5, 183:6 HARDIN ^[1] - 5:3 harm ^[2] - 117:21, 185:9 haul ^[1] - 176:8 Hawkins ^[1] - 3:7 HDMA ^[14] - 84:23, 97:3, 97:7, 97:9, 97:10, 97:15, 97:18, 97:20, 97:22, 98:6, 98:12, 99:1, 100:6,</p>				
G				
<p>Gary ^[3] - 99:8, 237:9, 246:6 gate ^[2] - 210:10, 210:16 gatekeeper ^[2] - 210:8, 210:12 gateway ^[2] - 193:5, 194:20 gear ^[1] - 28:10 general ^[9] - 26:6, 26:15, 67:16, 74:5, 75:21, 79:7, 141:11, 195:5, 216:13 generally ^[14] - 28:14, 28:16, 74:19, 78:17, 79:8, 110:19, 120:1,</p>	<p>122:19, 162:1, 162:25, 169:8, 170:4, 182:4, 198:1 generate ^[1] - 243:12 generated ^[1] - 243:13 generic ^[8] - 18:10, 18:13, 18:18, 18:20, 19:20, 20:8, 40:5 generics ^[1] - 239:11 generous ^[1] - 34:20 gentleman ^[1] - 236:15 gentlemen ^[3] - 17:11, 236:17, 237:10 geographic ^[6] - 11:14, 11:21, 76:9, 88:16, 88:18, 88:23 geographical ^[1] - 26:18 Georgia ^[2] - 24:9 get-go ^[1] - 129:9 Gina ^[2] - 16:1, 151:13 given ^[23] - 24:4, 34:14, 49:21, 103:24, 111:21, 117:17, 118:22, 127:13, 127:17, 128:3, 129:20, 131:11, 141:19, 154:25, 171:19, 182:16, 199:22, 216:1, 216:2, 216:6, 216:7, 229:6 glass ^[1] - 136:4 goal ^[1] - 31:6 governed ^[2] - 157:5, 196:20 government ^[2] - 33:10, 207:15 governmental ^[1] - 33:10 great ^[1] - 248:24 GRETCHEN ^[1] - 6:7 grew ^[1] - 200:7 ground ^[5] - 20:14, 26:12, 57:4, 62:4, 100:2 grounds ^[2] - 151:16, 209:5 group ^[9] - 22:7, 91:10, 175:24, 198:9, 207:23, 207:24, 207:25, 211:15 groups ^[3] - 23:21, 207:20, 207:21 growing ^[1] - 234:2 guarantee ^[1] - 119:13 guess ^[12] - 17:12, 45:2, 62:3, 100:11,</p>	<p>129:3, 132:25, 137:25, 148:13, 164:6, 164:24, 237:12 guidance ^[41] - 12:18, 39:19, 57:11, 57:13, 57:15, 57:17, 58:4, 94:25, 114:11, 114:12, 114:14, 115:15, 115:18, 117:24, 121:17, 121:19, 139:1, 145:4, 145:24, 146:7, 147:4, 147:7, 147:11, 147:16, 150:1, 152:3, 152:11, 152:12, 152:17, 153:16, 156:7, 156:9, 172:19, 173:2, 173:5, 173:14, 183:22, 186:10, 215:1, 215:23, 240:13 guy ^[1] - 17:10</p>	<p>100:16 head ^[2] - 210:21, 211:23 headed ^[1] - 25:2 heading ^[2] - 246:15, 246:18 headquarters ^[3] - 45:21, 45:23, 91:11 Headquarters ^[2] - 12:6, 13:22 Health ^[17] - 4:11, 5:2, 73:18, 74:2, 74:22, 76:21, 77:13, 78:2, 78:12, 80:6, 84:22, 93:2, 142:5, 142:13, 143:4, 143:13, 163:9 health ^[4] - 30:1, 61:17, 141:3, 190:24 healthcare ^[2] - 184:15, 184:19 Healthcare ^[2] - 97:10, 97:13 hear ^[11] - 8:10, 10:18, 38:23, 40:21, 49:12, 55:22, 73:15, 122:9, 128:24, 201:16, 245:5 heard ^[8] - 23:25, 24:11, 130:25, 133:14, 137:19, 155:20, 211:7, 212:7 hearing ^[10] - 115:8, 125:13, 130:20, 149:9, 149:12, 154:4, 187:14, 187:19, 189:7, 189:11 hearsay ^[36] - 12:13, 12:16, 12:24, 40:9, 53:2, 54:21, 55:2, 56:23, 57:3, 57:18, 75:15, 83:2, 83:4, 83:10, 94:21, 94:24, 95:3, 99:24, 100:2, 100:7, 100:13, 100:19, 100:22, 101:3, 101:17, 102:7, 155:23, 188:3, 188:6, 193:3, 193:4, 223:15, 223:18, 238:18 heart ^[1] - 34:13 heavy ^[1] - 131:14 held ^[2] - 12:5, 151:21 help ^[9] - 43:7, 43:9, 127:7, 136:23, 151:13, 163:6, 171:13, 190:16, 200:25 helped ^[1] - 169:15</p>	<p>helpful ^[5] - 113:8, 113:22, 114:24, 130:2, 227:2 helps ^[2] - 240:23, 248:14 hemorrhaging ^[1] - 31:8 hereby ^[1] - 49:1 herein ^[1] - 89:23 heroin ^[4] - 193:13, 195:12, 195:24, 196:4 Hester ^[5] - 98:14, 129:1, 136:10, 137:3, 137:23 HESTER ^[10] - 5:9, 129:2, 131:20, 132:1, 133:11, 134:2, 134:8, 136:11, 137:24, 138:10 high ^[4] - 25:10, 124:12, 234:8, 234:17 highlight ^[2] - 134:2, 237:8 highlighted ^[3] - 227:25, 237:20, 238:3 highlighting ^[1] - 129:3 highlights ^[1] - 194:13 highly ^[1] - 166:8 Highway ^[2] - 24:11, 24:18 Hilliard ^[8] - 237:9, 239:9, 239:10, 239:15, 246:6, 246:8, 246:18, 247:11 himself ^[1] - 111:13 historical ^[1] - 166:24 history ^[2] - 34:7, 128:15 hit ^[1] - 30:17 home ^[1] - 136:22 Homeland ^[1] - 187:13 homework ^[1] - 123:20 honest ^[1] - 236:20 Honor ^[221] - 7:7, 8:3, 8:6, 8:20, 8:25, 10:4, 11:11, 11:25, 12:14, 12:17, 13:5, 14:10, 14:22, 19:1, 19:2, 19:7, 19:22, 20:2, 22:20, 22:25, 26:6, 26:11, 27:3, 27:13, 28:2, 32:1, 33:1, 33:4, 33:17, 33:23,</p>

34:13, 34:24, 35:6, 35:12, 36:7, 36:8, 38:9, 40:18, 40:23, 41:20, 42:3, 42:14, 42:18, 42:24, 43:7, 44:6, 46:22, 49:10, 49:20, 49:24, 50:4, 50:6, 51:9, 51:10, 51:14, 51:15, 52:2, 53:2, 54:7, 54:20, 55:14, 55:21, 56:10, 56:18, 59:8, 62:2, 62:15, 63:2, 63:25, 64:4, 64:18, 65:1, 65:23, 67:19, 68:1, 68:5, 70:15, 71:3, 72:3, 72:21, 73:19, 74:7, 74:20, 75:5, 75:8, 75:14, 76:7, 76:11, 76:13, 78:24, 79:2, 79:19, 79:24, 84:13, 84:18, 85:11, 86:10, 86:13, 86:15, 86:25, 87:4, 87:9, 87:24, 88:11, 88:15, 92:13, 94:23, 98:3, 98:10, 98:16, 100:4, 100:21, 101:14, 103:2, 103:5, 104:17, 105:12, 106:4, 106:25, 107:10, 108:21, 109:10, 113:18, 113:24, 114:16, 115:4, 116:8, 116:11, 120:20, 121:4, 122:3, 122:8, 124:16, 126:20, 129:2, 129:3, 129:12, 129:21, 131:20, 132:2, 132:20, 132:23, 133:11, 134:2, 134:9, 134:21, 136:11, 137:1, 137:4, 137:15, 137:24, 138:9, 138:10, 139:3, 148:5, 150:12, 150:15, 150:18, 150:19, 153:4, 154:3, 154:11, 155:24, 159:22, 161:5, 161:24, 164:10, 165:11, 165:22, 166:6, 166:9, 170:12, 170:13, 170:24, 171:17, 173:17, 174:9, 176:5, 184:5, 187:6, 188:1, 188:3,	188:7, 188:14, 189:18, 189:22, 189:24, 192:4, 193:2, 193:9, 193:20, 194:1, 194:4, 194:10, 195:1, 195:13, 206:7, 206:23, 207:4, 207:5, 208:17, 208:25, 209:6, 209:14, 209:19, 209:25, 214:3, 214:11, 218:4, 218:7, 219:1, 219:9, 223:13, 223:17, 225:9, 225:12, 229:17, 238:16, 241:22, 248:21, 249:5 Honor's [1] - 65:4 HONORABLE [1] - 1:17 Honorable [1] - 7:1 hook [1] - 66:20 hope [4] - 92:18, 193:21, 215:25, 240:1 hopefully [4] - 52:12, 138:8, 142:17, 151:13 hospice [1] - 201:3 hospitals [2] - 199:8, 199:12 hour [9] - 123:24, 124:5, 126:2, 129:22, 129:25, 131:16, 133:6, 136:4, 219:16 hours [10] - 122:13, 122:14, 122:15, 122:21, 123:1, 123:3, 126:1, 133:6, 134:24, 245:15 House [2] - 187:12, 233:9 housekeeping [1] - 186:22 huge [1] - 13:18 Hundreds [1] - 110:4 hundreds [3] - 70:24, 71:19, 71:24 HUNTINGTON [1] - 1:4 Huntington [7] - 3:10, 4:1, 26:9, 38:5, 216:19, 216:21, 250:6 Huntington-Cabell [1] - 38:5 hydrocodone [31] -	13:15, 13:19, 16:9, 16:15, 17:25, 18:2, 18:10, 18:14, 25:8, 25:18, 27:22, 36:23, 37:1, 60:22, 60:25, 79:10, 79:11, 79:12, 79:13, 191:13, 196:25, 199:2, 199:17, 201:22, 202:1, 202:5, 202:13, 202:18, 222:2, 226:19, 239:11 Hydrocodone [1] - 201:22 I I(3)(ii) [1] - 69:16 I-75 [2] - 24:8, 24:22 idea [3] - 24:23, 119:23, 230:5 identification [2] - 116:5, 130:22 identified [8] - 16:9, 67:13, 74:24, 129:7, 178:8, 220:25, 221:19, 245:19 identifies [1] - 221:14 identify [16] - 18:12, 19:19, 64:12, 64:16, 76:19, 143:16, 151:9, 156:4, 168:10, 169:11, 183:24, 186:14, 186:19, 234:3, 234:8, 234:17 identifying [4] - 79:8, 104:7, 162:22, 183:2 ignorant [1] - 203:5 II [8] - 159:1, 159:2, 159:10, 159:11, 159:12, 202:6, 202:8, 247:17 III [9] - 159:1, 159:3, 159:11, 159:12, 202:5, 202:10, 247:20, 247:21 IIIs [1] - 159:3 illegal [1] - 119:22 illicit [4] - 70:25, 141:2, 234:11, 234:20 illicitly [3] - 190:19, 191:1, 191:5 illustrate [1] - 130:5 ILR [1] - 108:2 image [1] - 227:11 imbalance [1] - 166:18	Immediate [52] - 28:11, 28:13, 28:14, 29:4, 29:13, 29:18, 29:19, 29:25, 30:9, 30:19, 37:4, 59:12, 59:13, 59:19, 59:22, 60:6, 61:1, 61:5, 61:11, 63:3, 63:21, 65:17, 66:3, 67:9, 73:14, 73:16, 77:3, 77:11, 77:17, 77:23, 78:4, 80:8, 81:19, 81:25, 82:8, 86:5, 89:4, 89:5, 89:7, 89:8, 89:13, 91:4, 91:21, 92:5, 94:11, 96:13, 115:16, 148:21, 149:1, 185:25, 206:3 immediate [5] - 28:24, 29:14, 37:3, 77:2, 91:21 immediately [5] - 159:17, 221:5, 222:1, 229:12, 239:23 imminent [10] - 30:1, 30:7, 30:12, 30:17, 30:25, 61:14, 61:16, 61:21, 81:14, 89:11 impact [1] - 7:24 implement [1] - 166:19 implementation [1] - 45:19 implemented [3] - 48:25, 58:16, 231:10 implied [1] - 48:24 importance [3] - 127:13, 127:17, 153:1 important [16] - 119:20, 122:10, 124:24, 125:8, 125:25, 126:21, 127:14, 128:8, 128:13, 128:20, 160:20, 160:24, 202:7, 241:15, 245:12 impose [1] - 145:23 imposed [1] - 222:1 improper [3] - 53:19, 98:19, 195:17 IMS [2] - 163:9, 163:11 IN [2] - 1:1, 1:18 in-court [1] - 136:16 inasmuch [1] - 106:5 inclined [1] - 135:12 include [7] - 11:21,	26:17, 37:3, 69:19, 134:24, 180:17, 196:21 included [5] - 49:5, 49:16, 50:10, 59:19, 96:20 includes [5] - 55:25, 129:20, 130:23, 164:5 including [7] - 53:14, 75:25, 84:25, 89:18, 96:21, 130:6, 135:2 incoming [1] - 178:24 incorporated [1] - 76:1 incorporates [1] - 104:20 incorrect [1] - 53:16 increase [3] - 22:4, 199:2, 199:13 indefinite [1] - 132:19 indicate [6] - 8:17, 45:9, 82:24, 83:7, 104:10, 190:24 indicated [3] - 59:18, 83:11, 83:12 indicating [1] - 239:19 indication [2] - 43:22, 98:5 individual [3] - 90:21, 126:1, 189:25 individuals [2] - 133:15, 191:5 industrial [7] - 47:9, 47:20, 118:9, 197:8, 197:19, 199:23, 203:17 Industry [1] - 152:24 industry [10] - 26:24, 26:25, 85:7, 152:20, 194:10, 194:11, 194:14, 205:23, 207:2, 247:12 inform [2] - 98:8, 181:19 informant [1] - 166:13 informants [1] - 175:6 information [53] - 8:8, 8:13, 13:13, 27:25, 28:7, 40:25, 41:1, 41:22, 43:4, 49:15, 49:17, 50:12, 51:4, 51:7, 60:15, 66:14, 105:1, 105:18, 105:25, 106:7, 106:8, 107:2, 107:14, 107:16, 111:6, 112:8, 116:24, 120:24, 140:10, 157:12,
---	--	--	--	--

Ayme A. Cochran, RMR, CRR (304) 347-3128

<p>197:4 knowledge [40] - 21:8, 27:20, 28:4, 36:24, 38:19, 43:20, 45:8, 45:17, 52:16, 52:23, 52:24, 53:13, 54:9, 54:14, 56:7, 56:8, 56:10, 56:20, 56:23, 60:24, 62:12, 72:11, 76:9, 86:17, 90:22, 102:15, 102:25, 121:19, 146:12, 146:15, 152:11, 160:11, 161:6, 164:16, 168:9, 170:9, 183:22, 186:5, 221:4 known [1] - 49:18 knows [10] - 12:23, 20:4, 28:4, 28:5, 90:23, 101:15, 101:16, 111:14, 162:11, 162:12 KOUBA [1] - 3:14 Kyle [1] - 237:18</p>	<p>larger [1] - 167:25 last [25] - 58:8, 73:15, 76:5, 78:17, 78:19, 118:13, 124:5, 127:15, 127:25, 129:4, 130:17, 132:15, 133:20, 134:7, 141:5, 147:22, 177:11, 196:13, 204:14, 208:11, 222:15, 222:16, 223:2 late [4] - 137:8, 156:16, 213:2, 246:24 lately [1] - 125:6 LAURA [1] - 5:10 law [41] - 8:16, 28:20, 29:9, 31:16, 33:20, 41:21, 42:3, 43:3, 49:16, 82:16, 100:25, 106:7, 119:14, 119:16, 120:23, 133:13, 133:14, 133:16, 137:15, 137:16, 137:18, 137:19, 147:8, 147:19, 156:14, 165:9, 165:24, 166:3, 166:13, 167:22, 170:15, 174:11, 174:18, 184:23, 193:11, 193:14, 195:22, 206:20, 207:23, 208:10, 238:12 Law [4] - 3:4, 3:7, 3:12, 208:11 lawfully [3] - 117:13, 185:3, 186:6 lawyer [2] - 34:8, 229:23 lawyers [1] - 127:4 lay [9] - 27:5, 28:1, 52:5, 60:7, 62:9, 86:21, 98:21, 161:5, 161:10 layering [1] - 106:20 laying [1] - 27:25 lays [2] - 120:2, 120:3 lazy [1] - 134:6 lead [4] - 94:18, 112:25, 113:3, 141:7 leadership [2] - 12:8, 97:21 leading [3] - 175:8, 183:18, 185:13 leads [2] - 235:5, 235:7</p>	<p>learn [2] - 161:15, 175:19 learned [3] - 53:18, 54:18, 127:5 learning [1] - 161:25 least [7] - 15:19, 26:17, 84:1, 129:11, 138:20, 192:3, 225:25 leave [1] - 214:2 leaves [1] - 74:12 led [1] - 191:9 Lee [1] - 3:12 left [12] - 54:19, 123:13, 123:21, 124:10, 124:11, 124:23, 133:24, 207:11, 208:13, 211:17 legal [16] - 19:3, 19:25, 49:2, 56:13, 64:18, 65:2, 65:5, 65:13, 81:15, 102:19, 146:6, 147:9, 150:21, 173:16, 178:17, 206:22 legally [2] - 32:20, 88:5 legislative [1] - 233:15 legitimacy [1] - 119:7 legitimate [15] - 18:4, 47:8, 47:19, 89:18, 118:8, 186:12, 197:8, 197:11, 200:15, 201:2, 203:2, 203:7, 203:11, 203:16, 203:18 lend [1] - 34:18 length [2] - 55:24, 130:25 lengthened [1] - 126:16 Leon [2] - 2:4, 2:16 less [12] - 45:7, 123:25, 166:19, 190:25, 191:3, 200:20, 200:22, 232:14, 232:19, 232:21, 232:23, 232:25 lethal [1] - 117:19 letter [46] - 43:8, 43:12, 54:24, 116:18, 116:22, 117:2, 117:6, 117:25, 119:25, 120:2, 121:13, 121:14, 121:15,</p>	<p>141:23, 142:5, 142:7, 142:9, 142:19, 143:23, 143:24, 144:1, 144:2, 144:3, 144:5, 144:12, 144:14, 144:16, 144:18, 144:20, 144:22, 144:24, 145:5, 145:23, 146:4, 146:13, 147:23, 219:25, 220:2, 220:4, 220:8, 220:17, 221:9, 221:22, 222:25 letters [19] - 115:21, 115:24, 116:1, 116:2, 116:10, 146:16, 146:19, 146:25, 147:1, 147:3, 147:11, 147:17, 147:18, 147:19, 173:6, 173:7, 182:22, 182:23, 198:16 level [8] - 15:1, 91:10, 171:5, 183:7, 183:8, 196:16, 204:8, 231:11 levels [1] - 171:15 Levin [1] - 2:12 LEYIMU [1] - 4:8 license [2] - 119:17, 119:18 licensed [2] - 217:1, 225:24 life [2] - 201:3, 221:1 life-style [1] - 221:1 light [1] - 222:16 lightly [1] - 31:9 likely [5] - 107:7, 126:3, 127:21, 234:10, 234:19 limit [1] - 66:16 Limit [3] - 107:22, 108:4, 108:17 limitation [4] - 66:12, 66:16, 222:1, 222:6 limitations [3] - 41:25, 43:13, 55:9 limited [15] - 38:1, 38:19, 39:7, 43:6, 62:5, 73:24, 90:6, 90:17, 114:1, 116:12, 116:13, 224:3, 224:5, 224:7, 235:4 limiting [2] - 41:14, 75:3 limits [2] - 177:25,</p>	<p>178:4 LINDA [1] - 4:5 line [9] - 73:19, 79:22, 166:7, 198:13, 207:7, 213:12, 226:18, 229:15, 234:24 lines [4] - 213:5, 243:11, 243:14, 247:11 link [2] - 26:8, 26:9 Lisa [2] - 6:18, 250:3 List [1] - 247:24 list [11] - 123:19, 129:19, 129:21, 130:6, 130:9, 130:12, 130:14, 132:18, 149:2, 155:1, 202:16 listed [3] - 80:23, 229:2, 242:5 listen [1] - 245:9 listened [2] - 64:1, 245:8 listing [1] - 227:2 lists [1] - 164:14 literally [4] - 12:13, 14:25, 83:3, 205:13 litigants [1] - 128:14 litigation [1] - 208:4 live [2] - 40:15, 127:12 living [1] - 155:21 LLC [1] - 2:4 load [1] - 24:6 loaded [1] - 25:2 local [3] - 25:4, 137:19, 211:14 located [9] - 20:16, 20:17, 20:18, 45:10, 45:14, 45:15, 88:17, 216:19, 216:22 location [1] - 19:23 lodge [1] - 98:4 Logan [2] - 6:5, 6:12 look [63] - 14:2, 25:20, 30:13, 30:23, 39:17, 48:22, 57:11, 68:22, 87:8, 87:11, 92:21, 117:10, 118:13, 121:5, 121:10, 129:19, 133:24, 138:7, 141:5, 145:3, 149:2, 157:16, 173:21, 173:24, 177:23, 178:10, 179:8, 179:17, 179:19, 186:13, 186:15, 186:17, 192:21, 193:22, 197:3, 197:15,</p>
L				
<p>LA [1] - 3:8 lab [1] - 247:9 lack [8] - 56:20, 62:3, 66:10, 70:11, 102:24, 112:9, 130:5, 185:11 lag [2] - 159:15, 218:11 laid [7] - 55:3, 64:2, 66:18, 81:24, 87:24, 106:21, 155:11 Lakeland [18] - 15:23, 36:25, 37:14, 37:19, 38:1, 38:19, 39:7, 39:8, 39:13, 45:25, 77:13, 77:14, 86:6, 86:14, 87:2, 219:8, 220:12, 244:3 landed [1] - 112:7 Landover [2] - 46:5, 47:11 language [3] - 40:14, 226:10, 239:6 Lanier [1] - 3:4 large [14] - 9:13, 13:14, 25:8, 31:11, 43:19, 79:9, 84:7, 85:19, 89:14, 126:6, 145:19, 145:21, 168:13, 191:22 large-scale [1] - 191:22</p>				

<p>198:10, 198:15, 198:25, 216:7, 218:20, 218:23, 218:24, 220:18, 222:15, 223:2, 224:23, 225:2, 225:3, 225:15, 226:3, 226:18, 227:10, 227:11, 235:17, 236:19, 237:2, 242:3, 242:22, 245:16, 246:5, 246:14</p> <p>Look [1] - 233:12</p> <p>looked [13] - 17:10, 40:3, 40:4, 74:20, 92:25, 113:7, 167:24, 170:1, 190:6, 226:4, 236:11, 238:23, 244:15</p> <p>looking [29] - 14:18, 14:19, 14:20, 24:17, 25:14, 25:25, 37:21, 42:15, 55:13, 85:20, 92:8, 120:3, 138:15, 142:16, 142:19, 143:19, 164:25, 170:7, 174:2, 178:24, 179:13, 179:16, 182:8, 226:11, 227:5, 227:21, 233:3, 238:11</p> <p>looks [11] - 21:1, 32:8, 110:5, 111:3, 182:5, 182:6, 182:9, 182:15, 184:6</p> <p>lose [1] - 124:21</p> <p>lost [1] - 207:24</p> <p>loud [8] - 10:18, 36:19, 60:14, 67:5, 68:23, 118:4, 118:15, 145:3</p> <p>loved [1] - 207:24</p> <p>low [1] - 124:11</p> <p>lower [2] - 200:7, 200:8</p>	<p>mail [1] - 175:23</p> <p>MAINIGI [1] - 4:12</p> <p>maintain [15] - 11:14, 35:9, 46:9, 47:5, 47:16, 48:11, 69:8, 80:20, 118:23, 119:5, 173:3, 180:23, 180:25, 181:4, 201:1</p> <p>maintained [1] - 173:22</p> <p>maintaining [5] - 30:7, 117:16, 152:10, 173:10, 177:20</p> <p>MAJESTRO [15] - 2:6, 122:8, 124:4, 124:16, 124:20, 125:19, 127:8, 128:18, 132:23, 133:4, 134:1, 134:20, 136:3, 137:14, 138:8</p> <p>Majestro [9] - 2:6, 122:7, 124:3, 124:19, 129:7, 131:24, 132:22, 136:2, 136:12</p> <p>Majestro's [1] - 131:5</p> <p>major [3] - 41:22, 121:11, 191:10</p> <p>majority [4] - 30:15, 117:12, 121:9, 191:1</p> <p>managed [2] - 45:20, 45:22</p> <p>Management [3] - 97:11, 97:13, 188:15</p> <p>management [1] - 45:16</p> <p>manned [1] - 171:13</p> <p>manner [3] - 37:10, 75:2, 118:18</p> <p>manpower [3] - 23:15, 23:17, 185:21</p> <p>Manual [3] - 139:10, 139:11, 139:24</p> <p>manual [8] - 139:12, 139:13, 139:16, 139:18, 139:25, 140:1, 140:3, 230:19</p> <p>manuals [1] - 55:25</p> <p>manufacturer [2] - 30:6, 148:14</p> <p>manufacturers [11] - 117:3, 117:4, 117:15, 120:7, 144:25, 152:25, 176:24, 198:11, 207:13, 213:3, 235:1</p> <p>map [4] - 7:17, 7:18, 196:20, 198:2</p>	<p>Mapes [11] - 10:25, 11:1, 11:3, 12:10, 12:11, 12:23, 224:14, 224:24, 237:16, 238:8, 239:4</p> <p>Mapes's [1] - 238:23</p> <p>March [2] - 129:4, 192:18</p> <p>marching [1] - 138:1</p> <p>MARK [1] - 3:16</p> <p>marked [3] - 141:2, 219:13, 220:3</p> <p>market [1] - 70:25</p> <p>Maryland [1] - 46:5</p> <p>mask [1] - 138:15</p> <p>Massachusetts [1] - 94:15</p> <p>massive [3] - 22:4, 25:7, 194:18</p> <p>material [1] - 153:25</p> <p>materials [7] - 53:6, 53:7, 53:9, 153:21, 153:23, 198:11, 248:18</p> <p>math [5] - 17:25, 36:14, 124:13, 185:2, 185:4</p> <p>mathematical [1] - 200:10</p> <p>matter [7] - 54:4, 74:5, 157:2, 223:22, 229:9, 241:7, 250:5</p> <p>matters [1] - 120:21</p> <p>MCCLURE [1] - 6:3</p> <p>McConnell [1] - 126:2</p> <p>MCGINNNESS [1] - 4:2</p> <p>McKesson [101] - 5:8, 9:16, 10:14, 11:21, 12:4, 12:7, 12:19, 13:3, 13:22, 13:23, 14:7, 15:12, 15:17, 15:22, 16:22, 16:25, 17:3, 17:5, 18:6, 19:14, 20:9, 26:17, 31:19, 32:9, 35:17, 36:15, 36:24, 37:20, 40:12, 40:16, 44:13, 45:25, 47:5, 47:10, 47:16, 47:21, 47:22, 48:11, 48:16, 48:24, 58:12, 58:20, 58:25, 61:6, 84:14, 104:6, 109:8, 110:1, 212:11, 212:13, 212:16, 218:22, 219:6, 219:20, 219:22, 220:5, 220:9, 220:15, 220:19, 220:24, 221:4, 221:11,</p>	<p>221:20, 222:1, 222:6, 222:18, 223:7, 226:1, 226:25, 227:7, 227:22, 228:1, 228:8, 228:11, 228:13, 229:2, 230:14, 231:10, 236:3, 236:12, 236:23, 237:3, 237:8, 238:9, 239:23, 240:8, 240:11, 241:11, 242:15, 242:19, 242:23, 243:6, 243:12, 243:20, 244:9, 244:16, 246:3, 248:6, 248:9</p> <p>McKesson's [14] - 18:19, 19:19, 33:7, 37:14, 37:25, 39:6, 39:23, 46:2, 46:10, 49:2, 230:16, 236:9, 241:20, 246:19</p> <p>MDL [5] - 73:25, 74:1, 75:4, 76:19, 203:23</p> <p>mean [32] - 9:7, 9:8, 10:13, 18:11, 24:3, 24:13, 28:15, 44:1, 44:2, 48:8, 58:6, 63:18, 68:24, 70:22, 72:17, 80:18, 104:5, 119:19, 132:25, 135:11, 137:7, 138:1, 147:7, 148:25, 170:3, 183:6, 205:25, 219:10, 230:4, 231:17, 240:15</p> <p>meaning [2] - 23:8, 65:3</p> <p>meaningful [1] - 89:16</p> <p>means [9] - 30:2, 30:3, 41:15, 120:5, 127:15, 196:24, 203:17, 229:14, 245:11</p> <p>meant [1] - 60:4</p> <p>measures [1] - 117:14</p> <p>mechanical [1] - 6:19</p> <p>medical [8] - 22:9, 47:9, 47:19, 118:8, 197:8, 197:25, 203:16, 203:18</p> <p>medication [2] - 197:12, 201:4</p> <p>medicine [4] - 29:2, 190:22, 191:3, 191:9</p> <p>Medipharma [4] - 227:13, 227:14,</p>	<p>227:19, 227:21</p> <p>meet [5] - 58:11, 145:11, 181:22, 197:7, 199:14</p> <p>meeting [58] - 9:18, 9:19, 9:22, 10:11, 10:12, 10:13, 11:5, 11:6, 11:9, 12:4, 12:9, 12:11, 12:12, 13:2, 13:7, 13:12, 13:21, 13:22, 14:9, 14:16, 14:23, 14:25, 15:11, 31:20, 31:21, 31:22, 40:1, 40:14, 60:16, 60:18, 60:19, 60:23, 61:7, 85:4, 98:11, 98:25, 99:4, 99:9, 99:11, 99:23, 101:11, 101:20, 201:4, 212:13, 219:6, 219:20, 219:22, 220:14, 222:11, 222:17, 232:8, 237:10, 237:11, 238:13, 239:9, 239:10</p> <p>meetings [16] - 7:24, 28:6, 39:16, 85:2, 85:5, 85:8, 97:3, 99:12, 102:16, 103:14, 154:18, 212:7, 212:9, 220:9, 247:6, 248:1</p> <p>members [3] - 97:18, 97:19, 98:6</p> <p>memo [36] - 10:22, 11:4, 11:8, 14:6, 14:11, 15:11, 15:24, 16:5, 16:21, 58:5, 58:6, 219:5, 219:19, 221:17, 221:20, 221:22, 222:12, 224:11, 224:14, 224:24, 227:11, 229:2, 229:4, 231:19, 231:20, 231:23, 232:3, 232:8, 235:22, 235:23, 236:19, 236:23, 236:25, 239:3, 242:4</p> <p>memorandum [2] - 46:19, 89:24</p> <p>Memorandum [2] - 57:24, 96:11</p> <p>Memorandums [1] - 182:24</p> <p>memory [1] - 93:15</p> <p>mentioned [6] - 11:1, 14:12, 79:11,</p>
<p style="text-align: center;">M</p>				
<p>ma'am [9] - 10:9, 10:15, 29:11, 36:16, 44:16, 61:2, 147:25, 158:23</p> <p>Magazine [1] - 3:7</p> <p>magnify [1] - 226:15</p> <p>MAHADY [1] - 6:4</p> <p>Mahoney [4] - 237:9, 242:3, 242:8, 245:18</p>				

<p>125:11, 152:16, 184:14</p> <p>mess [1] - 192:4</p> <p>message [6] - 99:19, 100:6, 101:10, 101:13, 101:19, 101:21</p> <p>met [7] - 7:22, 19:14, 36:15, 84:22, 84:24, 97:7, 246:8</p> <p>methodology [1] - 130:1</p> <p>methods [1] - 190:20</p> <p>Miami [1] - 23:17</p> <p>mic [2] - 97:12, 158:16</p> <p>Michael [5] - 10:25, 11:3, 224:24, 237:16, 238:8</p> <p>MICHAEL [2] - 2:15, 3:9</p> <p>mid [1] - 246:24</p> <p>middle [1] - 151:12</p> <p>Midwest [1] - 24:10</p> <p>might [24] - 21:2, 22:11, 24:5, 72:24, 91:15, 95:2, 99:19, 104:15, 105:4, 105:19, 106:1, 106:16, 112:10, 118:7, 119:15, 135:12, 157:22, 160:7, 173:6, 174:12, 179:9, 201:17</p> <p>migration [1] - 193:12</p> <p>Mike [3] - 12:10, 12:11, 95:14</p> <p>MILDRED [1] - 3:3</p> <p>mill [6] - 22:10, 22:18, 23:1, 23:2, 23:5</p> <p>mill" [1] - 22:21</p> <p>milligram [1] - 24:17</p> <p>million [8] - 60:21, 171:12, 191:13, 210:25, 227:6, 227:22, 228:1, 239:18</p> <p>mills [12] - 22:14, 23:10, 24:5, 24:20, 24:24, 25:6, 25:24, 168:17, 191:18, 191:23, 202:3</p> <p>mind [6] - 45:4, 104:21, 143:6, 190:13, 205:14, 241:20</p> <p>mindful [2] - 136:1, 138:19</p> <p>minimum [1] - 224:1</p> <p>minute [9] - 20:14,</p>	<p>26:5, 41:18, 50:20, 86:8, 93:7, 100:1, 159:18, 170:18</p> <p>Minutes [3] - 208:14, 208:19, 209:9</p> <p>minutes [4] - 67:21, 98:11, 115:10, 241:4</p> <p>mischaracterizes [1] - 120:18</p> <p>misconduct [5] - 70:5, 70:14, 70:18, 70:23, 71:1</p> <p>misleading [2] - 164:14, 166:8</p> <p>miss [1] - 123:10</p> <p>missing [1] - 145:17</p> <p>misstatement [1] - 105:6</p> <p>misstates [1] - 218:4</p> <p>Mitchell [1] - 2:12</p> <p>mixed [1] - 115:7</p> <p>modest [1] - 159:23</p> <p>modification [1] - 37:23</p> <p>modified [4] - 23:8, 68:25, 69:2, 157:11</p> <p>modify [1] - 23:8</p> <p>modifying [1] - 221:5</p> <p>Mohr [1] - 137:9</p> <p>moment [5] - 85:11, 138:16, 145:2, 209:15, 233:6</p> <p>money [1] - 128:10</p> <p>monitor [2] - 19:20, 20:8</p> <p>Monitoring [19] - 18:16, 50:13, 53:23, 178:2, 178:14, 179:6, 179:14, 182:3, 182:12, 182:17, 182:19, 216:14, 230:17, 230:22, 231:1, 231:7, 231:9, 240:8, 240:12</p> <p>monitoring [9] - 18:20, 51:5, 52:18, 52:24, 55:7, 116:5, 117:1, 215:22, 216:13</p> <p>month [7] - 104:4, 110:11, 110:19, 159:20, 227:2, 228:2</p> <p>monthly [3] - 109:4, 111:22, 156:23</p> <p>months [11] - 36:14, 158:3, 170:5, 225:25, 228:20, 232:5, 232:14, 232:19, 232:21,</p>	<p>232:23, 235:11</p> <p>Moreover [1] - 117:14</p> <p>morning [11] - 7:7, 7:11, 7:12, 7:16, 82:10, 87:10, 115:13, 123:18, 126:11, 146:1, 249:2</p> <p>Morris [1] - 6:15</p> <p>mortar [3] - 20:18, 20:21, 22:2</p> <p>most [9] - 20:16, 20:17, 21:11, 23:13, 104:2, 123:23, 184:18, 210:17, 215:13</p> <p>motion [2] - 33:5, 56:19</p> <p>motives [2] - 208:20, 208:22</p> <p>Motley [5] - 2:9, 3:14, 4:3, 4:5, 4:8</p> <p>MOUGEY [1] - 2:12</p> <p>move [28] - 11:11, 14:23, 33:1, 34:3, 43:18, 57:6, 85:18, 86:21, 88:12, 102:9, 142:22, 143:16, 144:12, 150:12, 154:3, 154:10, 155:8, 165:11, 176:4, 178:12, 188:1, 189:18, 193:18, 196:11, 204:14, 214:15, 223:12, 225:7</p> <p>moved [3] - 22:15, 81:20, 176:17</p> <p>Moving [1] - 95:7</p> <p>moving [3] - 48:10, 55:25, 184:3</p> <p>MR [244] - 2:3, 2:6, 2:9, 2:12, 2:15, 3:9, 3:11, 3:16, 4:17, 5:9, 5:10, 5:13, 6:4, 8:3, 8:6, 8:12, 8:20, 8:25, 11:14, 11:24, 12:2, 12:13, 13:5, 14:10, 14:22, 17:19, 18:25, 19:6, 19:22, 27:23, 33:4, 33:14, 33:23, 34:1, 34:18, 35:8, 35:12, 38:3, 38:21, 40:8, 40:13, 40:19, 40:22, 41:14, 42:2, 42:8, 42:24, 43:6, 46:12, 46:21, 49:10, 49:13, 49:20, 49:23, 50:4, 50:15, 50:19, 50:21, 51:9, 51:13, 51:15, 52:2, 53:1,</p>	<p>53:5, 53:21, 54:20, 55:5, 55:21, 55:23, 56:6, 56:22, 56:24, 57:18, 62:2, 62:15, 63:5, 63:25, 64:6, 64:20, 64:22, 65:7, 66:7, 66:10, 67:1, 69:23, 70:6, 70:11, 71:3, 71:12, 72:2, 75:5, 75:11, 83:3, 87:17, 93:21, 94:2, 98:16, 99:16, 99:21, 99:24, 100:10, 101:1, 101:14, 102:3, 102:19, 102:22, 102:24, 104:17, 104:19, 104:23, 105:5, 105:7, 105:21, 106:4, 106:11, 106:14, 106:22, 107:6, 109:19, 111:12, 112:5, 112:11, 113:9, 113:24, 114:3, 120:20, 122:8, 124:4, 124:16, 124:20, 125:19, 127:8, 128:18, 129:2, 131:20, 132:1, 132:23, 133:4, 133:11, 134:1, 134:2, 134:8, 134:20, 136:3, 136:11, 137:14, 137:24, 138:8, 138:10, 145:25, 146:20, 147:6, 150:15, 150:19, 154:7, 155:10, 159:22, 161:24, 162:6, 162:10, 163:25, 165:11, 165:16, 165:22, 166:6, 166:21, 169:16, 170:12, 170:24, 173:12, 173:15, 174:9, 175:8, 178:16, 183:18, 185:13, 189:24, 190:3, 191:19, 193:1, 194:2, 194:4, 194:13, 194:21, 195:13, 195:18, 196:6, 196:8, 203:22, 205:13, 206:7, 206:10, 207:5, 208:17, 208:22, 209:6, 209:23, 209:25,</p>	<p>210:3, 213:4, 213:6, 214:3, 214:4, 214:5, 214:7, 214:8, 214:11, 214:14, 214:16, 214:17, 218:6, 218:9, 219:1, 219:3, 219:4, 219:12, 219:14, 219:15, 219:17, 223:12, 223:15, 223:16, 223:18, 223:19, 223:21, 223:24, 224:5, 224:8, 224:9, 224:20, 224:22, 225:7, 225:12, 225:14, 229:17, 229:22, 229:25, 238:16, 238:22, 241:21, 241:25, 248:21, 248:24, 249:5</p> <p>MS [355] - 3:3, 3:6, 3:14, 4:2, 4:5, 4:8, 4:12, 4:12, 4:15, 5:3, 5:4, 5:10, 6:3, 6:7, 6:14, 7:7, 7:15, 9:2, 10:3, 10:6, 10:17, 10:20, 10:21, 11:11, 12:3, 12:17, 12:25, 13:9, 13:10, 15:3, 15:7, 16:1, 16:3, 17:21, 18:5, 19:2, 19:7, 19:12, 20:2, 20:6, 22:20, 22:24, 23:3, 23:6, 26:6, 26:11, 26:12, 26:21, 27:3, 27:8, 27:11, 27:14, 27:16, 27:18, 28:2, 28:9, 31:25, 32:3, 33:1, 33:17, 34:13, 34:24, 34:25, 35:5, 35:15, 36:10, 38:9, 38:11, 38:13, 39:2, 40:18, 40:24, 41:5, 41:16, 41:20, 42:14, 42:18, 43:15, 44:5, 44:7, 46:15, 46:23, 47:2, 50:5, 50:7, 50:18, 50:25, 51:1, 51:17, 51:21, 51:23, 52:10, 52:11, 54:7, 54:15, 55:13, 56:9, 56:17, 57:7, 57:8, 57:22, 59:7, 59:10, 62:7, 62:11, 62:20, 62:21, 63:2, 63:17, 64:4, 64:18, 64:21, 65:1, 65:10, 65:14, 65:15, 65:20, 65:25, 66:22, 66:25,</p>
---	---	---	---	--

67:7, 67:19, 68:1, 68:3, 68:5, 68:7, 69:25, 70:8, 70:15, 70:19, 70:20, 71:8, 72:5, 72:21, 72:22, 73:4, 73:5, 73:6, 73:7, 73:19, 74:7, 74:19, 75:7, 75:14, 76:7, 76:18, 76:25, 78:24, 79:2, 79:6, 79:19, 79:24, 79:25, 81:15, 81:23, 82:2, 82:7, 83:2, 83:14, 84:16, 84:18, 84:19, 85:11, 85:14, 85:17, 86:10, 86:15, 86:25, 87:4, 87:9, 87:23, 88:2, 88:11, 88:14, 89:2, 90:8, 90:12, 90:20, 91:2, 92:11, 92:14, 92:23, 93:9, 93:25, 94:7, 94:21, 94:23, 95:18, 96:1, 98:3, 98:10, 98:23, 99:17, 99:22, 100:4, 100:21, 101:7, 101:8, 101:18, 102:9, 102:10, 103:2, 103:5, 103:9, 104:18, 104:20, 104:25, 105:8, 105:12, 105:15, 106:25, 107:12, 107:20, 108:5, 108:8, 108:9, 108:10, 108:12, 108:13, 108:20, 108:23, 109:1, 109:10, 109:12, 109:20, 109:24, 110:13, 110:15, 110:25, 111:5, 111:25, 112:24, 113:11, 113:14, 113:18, 113:19, 114:16, 114:22, 115:4, 115:11, 115:12, 116:8, 116:11, 116:14, 120:17, 121:12, 121:21, 121:24, 122:3, 137:1, 138:24, 139:3, 139:4, 142:11, 142:16, 142:18, 142:24, 143:1, 143:3, 143:5, 143:9, 143:14, 143:18, 146:3, 146:4, 146:5, 146:11, 147:2, 147:15, 148:3,	148:6, 150:12, 150:18, 151:2, 153:3, 153:5, 154:3, 154:6, 154:10, 154:12, 155:8, 155:14, 155:23, 156:1, 158:11, 158:14, 160:2, 160:7, 160:9, 161:5, 161:11, 161:12, 162:13, 162:24, 163:7, 164:10, 164:21, 166:9, 167:7, 167:17, 169:23, 171:2, 171:17, 171:24, 173:17, 173:19, 174:24, 175:11, 176:4, 176:10, 176:11, 183:21, 184:5, 184:11, 185:11, 185:16, 187:6, 187:7, 188:1, 188:3, 188:7, 188:21, 189:18, 189:21, 190:4, 190:9, 190:11, 191:25, 192:7, 193:9, 193:17, 193:20, 193:25, 194:8, 194:25, 195:7, 195:21, 196:11, 196:12, 204:3, 205:17, 206:8, 206:13, 206:22, 206:25, 207:4, 207:10, 208:20, 209:1, 209:14, 209:17, 209:19, 218:4, 219:9, 241:19 Mt [3] - 3:15, 4:4, 4:9 multiple [4] - 24:24, 84:24, 131:1 multipliers [2] - 183:16, 183:24 must [5] - 94:20, 95:5, 95:13, 134:18, 203:14	159:3, 159:11, 235:5 Narcotics [1] - 189:3 narrow [2] - 133:19, 214:23 national [7] - 19:15, 19:24, 38:18, 38:20, 63:23, 66:4, 190:23 nationwide [8] - 18:23, 40:3, 40:7, 45:5, 67:11, 82:1, 82:6, 86:18 nature [5] - 70:1, 70:22, 85:4, 126:15, 174:12 nearly [2] - 210:24, 211:4 necessarily [4] - 131:14, 164:5, 194:14 necessary [4] - 123:22, 128:11, 197:5, 197:19 need [36] - 36:1, 39:3, 52:21, 54:24, 55:14, 62:9, 65:22, 85:10, 87:25, 93:13, 101:15, 123:21, 124:19, 125:8, 130:23, 131:22, 132:21, 138:19, 169:15, 172:18, 181:17, 188:12, 196:21, 198:4, 198:14, 200:15, 200:16, 201:18, 202:11, 202:24, 202:25, 218:10, 226:16, 236:19, 245:23 needed [3] - 23:16, 151:4, 171:13 needs [8] - 70:17, 134:14, 157:13, 163:1, 197:8, 197:25, 199:14, 203:17 negative [1] - 180:17 neighborhood [1] - 205:1 nervous [1] - 50:5 netting [1] - 191:8 never [13] - 98:19, 126:25, 127:1, 162:8, 182:16, 184:1, 186:15, 197:20, 199:21, 222:6, 230:21, 231:6 Never [1] - 127:4 nevermind [1] - 192:20	Nevertheless [3] - 222:16, 223:3, 223:4 new [7] - 9:25, 121:15, 121:16, 137:9, 145:24, 199:16, 248:21 New [5] - 3:5, 3:8, 78:2, 142:6, 188:16 news [1] - 208:14 next [19] - 19:10, 48:10, 77:6, 85:18, 86:1, 115:5, 118:14, 118:15, 125:4, 136:1, 137:11, 140:18, 156:11, 186:23, 214:1, 221:9, 222:10, 229:21, 243:10 nexus [1] - 26:10 Nicholas [4] - 53:20, 64:21, 67:6, 102:23 NICHOLAS [36] - 6:11, 51:13, 53:21, 55:5, 56:24, 62:2, 62:15, 63:5, 63:25, 64:6, 64:20, 64:22, 65:7, 66:7, 66:10, 67:1, 69:23, 70:6, 70:11, 71:3, 71:12, 72:2, 102:24, 104:23, 105:7, 106:14, 112:5, 154:7, 159:22, 162:10, 166:6, 173:15, 185:13, 194:21, 195:18, 196:6 night [1] - 124:5 nine [5] - 123:24, 225:25, 228:2, 228:20, 242:5 nine-month [1] - 228:2 Ninth [1] - 4:6 Nobody [1] - 83:11 non [8] - 8:13, 100:7, 123:22, 160:17, 160:22, 161:1, 166:5, 209:3 non-compliance [1] - 209:3 non-controlled [2] - 160:17, 160:22 non-controls [1] - 161:1 non-cumulative [1] - 123:22 non-hearsay [1] - 100:7 non-privilege [1] - 8:13	non-public [1] - 166:5 noncompliance [3] - 37:25, 39:6, 100:24 None [1] - 83:11 none [3] - 33:14, 154:4, 166:17 Nonetheless [1] - 117:17 noon [3] - 115:6, 115:8, 136:19 north [1] - 25:3 note [12] - 33:18, 49:20, 72:25, 74:10, 74:15, 74:23, 75:16, 76:3, 76:11, 106:11, 136:5, 137:17 noted [2] - 238:14, 239:2 notes [1] - 86:11 Nothing [1] - 235:19 nothing [5] - 56:24, 111:9, 194:14, 209:19 Notice [1] - 194:14 notice [17] - 12:20, 29:1, 58:10, 94:25, 95:6, 95:7, 100:22, 116:13, 150:20, 150:23, 181:16, 194:10, 194:23, 223:19, 224:2, 224:6, 232:25 notified [2] - 146:25, 221:10 notifies [1] - 223:5 notwithstanding [2] - 60:11, 60:15 Notwithstanding [1] - 89:14 November [1] - 221:10 number [36] - 16:12, 18:1, 28:17, 33:5, 33:6, 37:18, 45:3, 73:4, 73:5, 73:6, 85:24, 108:5, 108:6, 108:11, 124:11, 126:9, 139:5, 142:24, 154:25, 163:10, 187:3, 190:7, 192:24, 192:25, 193:24, 199:8, 201:23, 201:24, 201:25, 202:14, 202:15, 219:14, 233:4 Number [12] - 73:2, 77:7, 77:19, 78:6, 79:17, 80:1, 80:14, 96:6, 98:1, 120:9, 120:10, 193:20
	N			
	name [4] - 18:18, 99:6, 230:16, 234:8 names [9] - 16:11, 16:13, 155:1, 224:12, 224:15, 224:18, 225:4, 225:10, 237:9 narcotic [1] - 235:4 narcotics [5] - 159:1,			

<p>numbering [1] - 233:18</p> <p>numbers [5] - 17:7, 134:23, 183:5, 183:6, 184:21</p> <p>NW [6] - 2:10, 4:6, 4:13, 4:15, 5:5, 5:12</p> <p>NY [1] - 3:5</p>	<p>39:1, 41:3, 42:22, 46:12, 50:23, 51:13, 51:16, 52:2, 53:3, 54:5, 54:20, 57:5, 57:18, 63:5, 64:11, 64:23, 64:25, 66:19, 67:4, 67:5, 70:6, 71:16, 72:2, 73:19, 75:18, 76:24, 79:4, 79:21, 79:22, 86:13, 87:2, 88:13, 88:24, 93:7, 95:3, 98:4, 99:16, 100:2, 101:5, 101:14, 102:8, 103:7, 105:8, 105:17, 106:25, 111:15, 112:16, 114:4, 114:6, 116:13, 133:2, 136:10, 145:25, 146:8, 146:20, 146:22, 150:14, 150:15, 154:4, 154:8, 155:9, 155:10, 155:23, 159:23, 161:9, 163:4, 163:25, 164:6, 164:11, 164:18, 166:10, 169:16, 169:21, 171:21, 173:12, 174:9, 175:8, 178:16, 178:21, 183:18, 188:2, 189:21, 189:22, 191:21, 194:13, 195:4, 195:20, 196:7, 196:9, 206:10, 206:24, 207:9, 209:4, 209:13, 223:14, 225:8, 225:11, 225:12</p> <p>objections [23] - 33:22, 34:2, 38:22, 43:10, 55:17, 74:23, 74:24, 75:16, 76:4, 88:19, 89:1, 120:25, 123:5, 126:10, 126:12, 126:15, 126:16, 126:25, 134:23, 135:14, 171:18, 193:1</p> <p>objective [1] - 138:1</p> <p>obligation [3] - 167:5, 167:9, 173:10</p> <p>obligations [7] - 49:2, 63:12, 115:21, 116:24, 144:9, 155:21, 171:14</p>	<p>observations [3] - 104:6, 180:18, 195:11</p> <p>observe [6] - 62:13, 62:22, 178:1, 195:24, 196:3, 206:16</p> <p>observed [7] - 70:10, 86:20, 95:17, 193:12, 205:19, 206:17, 206:18</p> <p>obtained [1] - 165:3</p> <p>obtaining [1] - 191:1</p> <p>Obviously [1] - 229:13</p> <p>obviously [4] - 93:10, 137:2, 189:24, 206:11</p> <p>Occam's [1] - 57:4</p> <p>occasion [1] - 83:23</p> <p>occur [2] - 71:1, 200:23</p> <p>occurred [5] - 15:4, 75:13, 91:9, 184:1, 215:9</p> <p>occurs [1] - 140:20</p> <p>October [10] - 16:7, 36:21, 212:1, 226:25, 227:19, 232:13, 232:16, 232:22</p> <p>OF [2] - 1:1, 1:4</p> <p>offer [5] - 34:21, 65:5, 193:1, 194:10, 224:1</p> <p>offered [6] - 75:17, 76:3, 94:24, 167:11, 184:21, 188:5</p> <p>offering [3] - 193:16, 194:7, 223:21</p> <p>office [5] - 35:1, 149:1, 168:4, 188:9, 210:23</p> <p>Office [4] - 154:19, 204:19, 210:21, 211:23</p> <p>Office's [2] - 140:21, 176:21</p> <p>office's [2] - 35:2, 188:10</p> <p>Officer [1] - 161:14</p> <p>officer [1] - 156:14</p> <p>officers [2] - 23:19, 211:14</p> <p>Offices [3] - 140:8, 140:9, 140:13</p> <p>offices [1] - 140:16</p> <p>Official [2] - 250:2, 250:3</p> <p>official [10] - 147:4, 147:7, 147:11, 154:1, 187:20,</p>	<p>187:21, 189:12, 191:14, 192:14, 194:9</p> <p>officials [3] - 36:20, 151:16, 151:18</p> <p>often [3] - 156:22, 176:15, 195:25</p> <p>old [1] - 166:12</p> <p>on-going [2] - 113:4, 228:15</p> <p>on-site [5] - 178:2, 230:21, 231:2, 231:4, 231:6</p> <p>Once [1] - 228:21</p> <p>once [1] - 149:3</p> <p>One [3] - 5:11, 121:6, 188:22</p> <p>one [111] - 9:12, 15:19, 17:10, 18:21, 19:23, 23:21, 27:2, 33:5, 33:21, 34:2, 34:8, 34:15, 37:5, 38:4, 38:13, 39:21, 43:21, 57:4, 57:9, 57:13, 57:24, 58:14, 58:22, 59:18, 60:17, 62:18, 64:23, 66:23, 69:4, 73:10, 75:18, 77:25, 78:19, 82:22, 90:10, 97:23, 98:12, 101:2, 102:5, 112:21, 117:20, 119:10, 120:12, 120:15, 121:1, 121:2, 121:8, 123:4, 125:18, 127:9, 130:7, 132:7, 132:25, 133:24, 134:8, 135:3, 135:16, 136:5, 137:2, 138:14, 139:19, 141:5, 142:22, 143:8, 143:9, 143:11, 153:10, 153:11, 156:10, 165:8, 166:1, 168:22, 183:2, 185:5, 186:8, 188:12, 190:25, 191:10, 191:12, 192:21, 193:16, 193:17, 194:21, 195:23, 196:1, 197:5, 201:22, 201:23, 201:24, 201:25, 202:15, 203:9, 212:15, 219:15, 224:18, 225:18, 227:13, 227:25, 229:1, 229:6, 229:7, 231:5,</p>	<p>231:21, 236:18, 236:20, 237:14, 237:21, 238:2, 238:3, 240:22</p> <p>one-third [1] - 123:4</p> <p>ones [6] - 135:18, 180:5, 207:24, 210:10, 215:9, 216:22</p> <p>ongoing [1] - 175:16</p> <p>oops [1] - 188:12</p> <p>open [8] - 12:9, 113:4, 158:9, 210:10, 210:16, 218:1, 218:18, 228:9</p> <p>operate [2] - 45:1, 234:4</p> <p>operated [4] - 19:14, 45:14, 48:14, 80:23</p> <p>operates [1] - 231:16</p> <p>operating [16] - 19:18, 22:8, 25:24, 30:3, 40:7, 45:5, 58:4, 63:10, 64:15, 67:14, 182:6, 182:9, 182:14, 182:15, 184:25, 216:20</p> <p>operation [2] - 26:16, 88:21</p> <p>operational [1] - 182:5</p> <p>operations [4] - 23:16, 220:20, 230:19, 248:10</p> <p>opinion [22] - 19:25, 38:7, 56:3, 57:1, 166:24, 169:17, 169:18, 169:19, 173:12, 173:13, 178:17, 178:18, 191:20, 193:5, 193:10, 194:20, 196:8, 203:22, 205:13, 227:16</p> <p>opinions [3] - 42:10, 130:1, 164:2</p> <p>opioid [7] - 126:22, 195:25, 200:6, 207:13, 208:4, 212:4</p> <p>opioids [6] - 21:25, 69:19, 79:12, 193:13, 195:11, 196:5</p> <p>opportunity [1] - 28:19</p> <p>opposed [5] - 112:2, 112:13, 146:7, 223:22, 239:16</p> <p>option [1] - 136:7</p> <p>oral [1] - 241:16</p> <p>Order [153] - 18:16,</p>
--	--	---	--	--

<p>28:11, 28:13, 28:14, 28:15, 28:16, 28:25, 29:4, 29:5, 29:15, 29:16, 29:17, 29:18, 29:19, 29:20, 29:25, 30:21, 31:5, 31:9, 31:10, 31:12, 31:19, 32:9, 32:10, 32:15, 32:18, 32:20, 33:2, 35:16, 35:18, 36:12, 36:18, 37:2, 37:4, 37:6, 37:12, 37:17, 37:24, 39:9, 39:12, 41:8, 43:18, 43:24, 45:25, 46:6, 46:13, 46:17, 50:13, 53:22, 58:20, 58:21, 58:24, 58:25, 59:2, 59:4, 59:12, 59:13, 59:16, 59:19, 59:22, 59:23, 59:24, 60:6, 60:7, 61:1, 61:5, 61:6, 61:10, 61:11, 63:3, 63:4, 63:21, 63:22, 65:17, 66:2, 66:3, 67:9, 69:3, 71:18, 71:19, 71:23, 71:25, 73:14, 73:16, 76:1, 77:3, 77:6, 77:11, 77:16, 77:17, 77:23, 77:24, 78:3, 78:4, 78:10, 78:13, 78:20, 86:5, 86:6, 88:5, 89:5, 89:6, 89:8, 89:9, 89:12, 89:13, 91:4, 91:5, 91:21, 91:22, 92:5, 92:6, 93:3, 94:11, 95:7, 95:8, 96:13, 96:14, 148:21, 148:22, 149:2, 170:25, 173:24, 178:1, 178:14, 179:6, 179:13, 182:2, 182:12, 182:17, 182:19, 206:4, 216:14, 230:17, 230:22, 231:1, 231:6, 231:8, 240:8, 240:12, 240:19, 241:10, 245:20, 246:23, 247:6</p> <p>order [53] - 14:17, 29:9, 34:3, 51:5, 52:17, 52:24, 55:7, 67:11, 68:25, 69:1, 69:2, 75:2, 76:12, 103:21, 103:22, 103:23, 103:25, 104:10, 112:1, 112:13, 112:19,</p>	<p>112:20, 112:23, 112:25, 113:2, 115:2, 116:5, 116:25, 118:25, 145:12, 145:20, 147:23, 150:7, 150:9, 151:5, 152:4, 152:12, 158:4, 169:19, 172:11, 172:16, 172:20, 172:25, 183:10, 196:21, 211:18, 215:2, 215:22, 216:12, 235:18</p> <p>ordered [1] - 89:15</p> <p>ordering [8] - 57:2, 145:19, 145:21, 160:25, 186:13, 186:20, 191:5, 204:10</p> <p>Orders [30] - 29:13, 30:9, 30:11, 30:20, 31:2, 46:1, 69:12, 80:7, 80:8, 80:19, 81:18, 81:19, 81:25, 82:1, 82:5, 82:8, 82:9, 89:3, 89:4, 115:16, 115:17, 185:24, 185:25, 206:2, 206:3, 246:16, 246:19, 247:3, 247:4, 247:8</p> <p>orders [74] - 13:17, 18:12, 20:23, 28:24, 48:9, 48:17, 49:1, 49:3, 64:13, 64:16, 69:15, 81:9, 82:21, 89:21, 95:22, 95:23, 95:25, 102:18, 103:11, 103:14, 103:15, 103:19, 104:2, 104:3, 104:7, 104:9, 104:10, 104:12, 105:19, 106:1, 106:16, 107:3, 107:15, 107:17, 109:25, 114:11, 116:5, 118:5, 118:7, 119:7, 119:20, 138:1, 140:4, 140:25, 141:1, 145:9, 145:17, 150:2, 152:7, 152:9, 156:4, 159:14, 159:17, 169:11, 169:12, 173:4, 178:7, 178:25, 179:10, 183:3, 183:16, 183:24, 186:14, 214:19, 217:18,</p>	<p>217:19, 222:3, 244:4, 244:11, 244:17, 244:21, 247:15</p> <p>organization [1] - 97:16</p> <p>originally [2] - 24:8, 65:21</p> <p>Orlando [2] - 67:13, 69:9</p> <p>Orleans [1] - 3:8</p> <p>otherwise [3] - 9:1, 58:15, 124:13</p> <p>ought [1] - 33:12</p> <p>out-manned [1] - 171:13</p> <p>out-of-court [1] - 188:4</p> <p>outgoing [1] - 178:25</p> <p>outrageous [1] - 95:11</p> <p>outside [12] - 75:17, 133:3, 133:4, 170:15, 179:6, 181:12, 195:16, 203:22, 221:11, 234:4, 238:17, 239:20</p> <p>Outside [1] - 195:18</p> <p>overall [1] - 198:16</p> <p>overlap [1] - 130:9</p> <p>overlapping [1] - 130:23</p> <p>overrule [23] - 11:17, 17:22, 20:3, 26:14, 26:18, 38:25, 41:3, 42:22, 64:10, 66:19, 71:16, 76:24, 88:23, 95:3, 111:14, 112:16, 120:25, 146:22, 163:3, 164:17, 178:21, 191:21, 206:24</p> <p>Overrule [1] - 79:4</p> <p>Overruled [16] - 72:4, 81:17, 82:3, 83:10, 90:9, 95:19, 102:21, 103:3, 109:22, 111:1, 113:13, 114:18, 121:22, 189:23, 203:24, 238:20</p> <p>overruled [21] - 11:18, 11:23, 14:13, 15:5, 28:3, 42:12, 46:25, 62:17, 63:7, 71:6, 79:21, 90:23, 103:6, 103:7, 126:12, 147:10, 155:13, 155:25, 218:8,</p>	<p>241:23</p> <p>oversaw [2] - 198:8, 210:22</p> <p>oversee [1] - 210:9</p> <p>overseeing [2] - 198:19, 210:5</p> <p>overwhelming [1] - 117:12</p> <p>own [6] - 90:21, 113:25, 166:20, 169:11, 182:10, 236:4</p> <p>owned [2] - 48:14, 80:23</p> <p>Oxy [4] - 23:25, 24:8, 24:17</p> <p>oxy [3] - 24:4, 25:23</p> <p>oxycodone [8] - 25:10, 25:11, 25:18, 27:21, 89:21, 199:2, 199:17, 200:13</p> <p>Oxycodone [1] - 26:2</p>	<p>P-23733 [3] - 44:5, 44:8, 45:25</p> <p>P-23736 [5] - 148:7, 150:13, 226:5, 226:14, 227:17</p> <p>P-27 [1] - 157:6</p> <p>P-28 [1] - 86:1</p> <p>P-28007 [1] - 109:9</p> <p>P-28091 [1] - 108:3</p> <p>P-42383 [1] - 192:2</p> <p>P-42747 [3] - 108:20, 109:3, 109:25</p> <p>P-9116 [2] - 219:16, 219:18</p> <p>p.m [2] - 184:9, 249:6</p> <p>P.O [2] - 5:14, 6:8</p> <p>PA [3] - 6:6, 6:13, 6:15</p> <p>package [2] - 61:19, 144:11</p> <p>packaged [1] - 148:15</p> <p>packager [1] - 148:14</p> <p>packet [3] - 85:19, 141:24, 240:23</p> <p>page [44] - 14:3, 14:4, 16:2, 16:5, 48:10, 48:21, 72:25, 73:8, 73:10, 77:6, 79:20, 86:1, 96:7, 116:16, 117:6, 117:9, 119:25, 120:1, 140:3, 140:23, 145:13, 151:12, 190:7, 192:10, 192:21, 193:16, 193:17, 193:19, 193:23, 220:17, 221:9, 222:10, 224:25, 225:2, 225:3, 235:25, 236:18, 237:1, 237:2, 239:5, 242:10, 243:10, 243:14</p> <p>Page [51] - 15:24, 32:13, 32:15, 36:17, 47:4, 47:14, 47:25, 48:22, 57:25, 60:10, 60:12, 68:21, 79:17, 80:14, 81:1, 140:2, 144:13, 151:11, 154:22, 190:6, 190:7, 194:2, 194:3, 194:4, 213:5, 213:11, 222:23, 222:24, 222:25, 226:9, 226:14, 227:16, 232:12, 233:12, 233:18, 241:2, 241:11, 242:1, 242:4, 242:7,</p>
P				
<p>P-00009 [1] - 68:4</p> <p>P-00013 [1] - 92:11</p> <p>P-00016 [3] - 31:25, 32:5, 35:13</p> <p>P-00032 [4] - 116:7, 141:23, 143:1, 144:12</p> <p>P-00049 [2] - 59:7, 59:11</p> <p>P-00298 [2] - 84:17, 96:25</p> <p>P-01207 [3] - 187:5, 188:1, 190:5</p> <p>P-016726 [2] - 187:4, 189:19</p> <p>P-02291 [2] - 153:3, 154:3</p> <p>P-08861 [1] - 139:2</p> <p>P-08873 [3] - 72:20, 72:23, 85:19</p> <p>P-09116 [2] - 10:3, 11:12</p> <p>P-09399 [1] - 92:12</p> <p>P-09616 [2] - 154:10, 155:8</p> <p>P-10 [1] - 139:7</p> <p>P-1200 [1] - 2:7</p> <p>P-1207 [4] - 233:4, 233:5, 233:8, 233:18</p> <p>P-14288 [2] - 108:10, 108:16</p> <p>P-16 [1] - 240:19</p> <p>P-16726 [1] - 188:24</p> <p>P-19525 [1] - 121:25</p> <p>P-23726 [1] - 148:3</p>				

<p>242:12, 244:1, 244:22, 245:16, 245:22, 246:5, 246:15, 248:3, 248:8, 248:12</p> <p>Pages [2] - 32:19, 33:2</p> <p>paid [5] - 161:4, 161:23, 207:22, 208:3, 208:6</p> <p>pain [8] - 22:4, 22:5, 22:6, 22:7, 22:18, 23:3, 23:9, 200:16</p> <p>palliative [2] - 200:16, 201:2</p> <p>Papantonio [1] - 2:12</p> <p>paper [1] - 192:8</p> <p>papers [1] - 17:10</p> <p>Paragraph [22] - 36:17, 48:1, 48:15, 48:20, 57:25, 58:2, 58:8, 60:10, 68:22, 80:14, 81:6, 81:7, 89:12, 90:16, 92:16, 92:17, 92:20, 92:22, 120:8, 120:9, 145:8</p> <p>paragraph [36] - 36:18, 47:12, 47:15, 48:22, 68:23, 80:15, 90:13, 92:25, 117:11, 118:2, 118:13, 118:14, 118:15, 118:20, 119:3, 140:8, 140:14, 140:15, 141:6, 145:14, 145:15, 190:14, 190:15, 190:17, 220:18, 221:10, 222:15, 222:16, 223:2, 236:2, 239:8, 244:2, 245:18, 245:21, 245:22, 248:13</p> <p>paragraphs [1] - 237:2</p> <p>Paragraphs [1] - 145:3</p> <p>part [25] - 19:9, 21:11, 25:20, 35:4, 53:21, 73:15, 141:24, 145:5, 153:10, 154:1, 171:22, 173:10, 180:3, 181:1, 186:24, 192:20, 197:21, 197:23, 199:6, 210:11, 210:17, 216:9, 216:11, 240:2, 247:3</p> <p>participants [1] -</p>	<p>128:16</p> <p>participated [1] - 85:2</p> <p>participation [1] - 246:19</p> <p>particular [25] - 9:12, 24:16, 25:17, 39:18, 47:8, 47:18, 55:15, 58:17, 75:8, 75:20, 84:20, 86:11, 86:17, 86:21, 88:16, 95:9, 106:16, 130:22, 147:23, 147:24, 161:7, 162:4, 170:8, 205:8</p> <p>particularly [3] - 74:11, 75:19, 205:6</p> <p>parties [6] - 43:10, 74:16, 126:24, 127:14, 129:17, 132:8</p> <p>parts [1] - 197:21</p> <p>party [8] - 33:19, 34:8, 42:18, 55:19, 74:3, 163:14, 163:15, 165:4</p> <p>pass [1] - 136:6</p> <p>passage [1] - 171:20</p> <p>passed [5] - 22:1, 136:5, 153:7, 215:12, 219:12</p> <p>passing [1] - 220:3</p> <p>past [7] - 24:9, 57:17, 121:20, 123:8, 152:13, 157:18, 183:16</p> <p>patient [15] - 21:2, 21:6, 21:7, 21:9, 21:12, 21:19, 197:12, 197:20, 197:22, 197:23, 199:14, 199:21, 200:21, 202:25</p> <p>patients [15] - 184:25, 197:11, 197:16, 199:10, 199:12, 200:2, 200:15, 201:2, 201:3, 201:5, 201:18, 203:2, 203:7, 203:11, 203:18</p> <p>patterns [4] - 13:16, 186:14, 186:20, 204:10</p> <p>PAUL [2] - 2:3, 5:9</p> <p>Paul [1] - 220:5</p> <p>Pause [3] - 85:13, 94:3, 209:18</p> <p>pay [3] - 22:12, 150:4, 208:2</p> <p>payers [2] - 163:15,</p>	<p>165:7</p> <p>PDAC [1] - 192:12</p> <p>Peabody [1] - 94:14</p> <p>PEARL [1] - 3:6</p> <p>pending [1] - 56:19</p> <p>Pensacola [1] - 2:14</p> <p>Pentagon [1] - 188:14</p> <p>people [24] - 23:20, 24:4, 25:1, 53:15, 54:1, 93:24, 94:19, 136:20, 137:18, 149:2, 155:1, 156:23, 200:9, 200:12, 200:13, 200:24, 201:16, 201:25, 202:25, 205:1, 205:2, 210:13, 238:2</p> <p>per [3] - 34:8, 108:24</p> <p>percent [16] - 122:14, 122:16, 125:3, 184:24, 185:5, 190:24, 190:25, 200:20, 200:22, 201:16, 201:17, 201:19, 202:22, 203:4, 222:3</p> <p>percentage [2] - 184:21, 201:13</p> <p>perfect [3] - 36:8, 201:21</p> <p>perfectly [1] - 112:15</p> <p>perform [2] - 212:24, 213:13</p> <p>performed [1] - 177:15</p> <p>perhaps [2] - 142:24, 174:11</p> <p>period [39] - 8:2, 16:10, 16:14, 26:3, 36:21, 53:14, 53:17, 53:18, 54:10, 55:10, 62:25, 63:6, 64:8, 105:11, 110:14, 126:7, 129:10, 159:23, 160:1, 160:5, 168:6, 168:7, 175:19, 178:25, 179:3, 183:5, 199:16, 211:22, 213:21, 214:13, 215:1, 215:23, 215:24, 218:1, 218:2, 228:2, 232:11, 233:1</p> <p>periodically [1] - 176:13</p> <p>periods [2] - 141:6, 141:7</p> <p>permission [3] -</p>	<p>143:15, 158:12, 188:24</p> <p>permitted [4] - 41:19, 65:3, 75:5, 86:20</p> <p>person [5] - 33:21, 34:2, 118:25, 141:8, 237:11</p> <p>personal [10] - 42:25, 45:8, 56:20, 66:13, 76:9, 90:21, 102:24, 113:25, 187:15, 189:8</p> <p>personally [9] - 168:1, 217:23, 217:24, 220:1, 242:18, 242:22, 243:7, 244:7, 246:2</p> <p>personnel [4] - 23:22, 210:22, 211:4, 220:21</p> <p>perspective [2] - 130:15, 207:3</p> <p>pertaining [2] - 216:11, 216:12</p> <p>PETER [1] - 2:12</p> <p>Pharmaceutical [2] - 148:2, 152:24</p> <p>pharmaceutical [1] - 152:20</p> <p>pharmaceuticals [1] - 190:25</p> <p>Pharmaceuticals [1] - 148:11</p> <p>pharmacies [86] - 9:5, 11:16, 13:15, 13:19, 14:8, 14:11, 14:16, 16:8, 16:11, 20:13, 20:15, 20:16, 20:17, 20:18, 21:21, 22:2, 22:18, 22:19, 23:9, 24:20, 24:25, 25:4, 36:22, 37:1, 39:18, 60:22, 60:25, 61:8, 79:10, 84:8, 88:17, 95:9, 95:10, 95:11, 96:21, 111:20, 117:15, 151:17, 167:25, 168:15, 168:16, 171:10, 171:11, 171:16, 175:24, 191:7, 199:12, 204:9, 215:5, 215:13, 215:16, 216:17, 216:25, 217:4, 217:18, 217:20, 218:1, 218:12, 219:8, 220:20, 221:14, 221:15, 221:20, 221:23,</p>	<p>222:2, 222:3, 222:18, 222:20, 223:6, 224:15, 225:15, 225:18, 225:22, 228:5, 228:8, 229:2, 230:4, 230:6, 233:23, 234:10, 234:19, 245:19, 246:3, 248:11</p> <p>pharmacies [1] - 13:20</p> <p>pharmacists [1] - 26:25</p> <p>pharmacy [36] - 16:14, 17:18, 17:24, 20:21, 20:22, 21:5, 21:16, 28:19, 29:2, 29:10, 30:5, 89:15, 89:20, 89:22, 119:13, 120:14, 121:6, 145:19, 145:21, 163:16, 163:18, 163:20, 170:8, 186:18, 191:12, 204:12, 216:20, 225:4, 227:6, 227:12, 228:11, 229:11, 230:1, 233:25</p> <p>Pharmacy [2] - 192:12, 225:19</p> <p>pharmacy's [1] - 161:4</p> <p>phase [2] - 25:9, 131:14</p> <p>phentermine [1] - 69:13</p> <p>Philadelphia [2] - 6:6, 6:13</p> <p>phone [1] - 21:12</p> <p>phrased [1] - 19:5</p> <p>physical [1] - 21:18</p> <p>pick [6] - 7:20, 18:17, 125:25, 145:20, 180:4, 246:10</p> <p>picked [3] - 33:9, 168:12, 168:13</p> <p>picking [6] - 18:10, 18:13, 18:22, 18:23, 40:5, 239:11</p> <p>picture [1] - 136:3</p> <p>PIFKO [1] - 3:16</p> <p>pill [12] - 16:19, 22:14, 22:18, 22:21, 23:4, 24:5, 24:24, 25:24, 168:16, 191:18, 191:23, 202:3</p> <p>pills [11] - 16:22, 17:1, 24:19, 170:10,</p>
---	--	---	--	--

<p>191:3, 191:6, 191:8, 218:15, 227:6, 227:22, 228:1 pinpointed [1] - 103:16 place [15] - 9:19, 55:15, 67:18, 98:25, 99:13, 118:19, 122:1, 149:5, 176:15, 182:21, 191:24, 200:1, 222:7, 248:23, 248:24 placed [1] - 66:12 places [3] - 26:8, 140:12, 216:24 placing [1] - 118:25 Plaintiff [5] - 1:5, 1:11, 2:2, 3:2, 4:1 plaintiffs [21] - 76:19, 122:15, 123:1, 123:13, 129:19, 129:23, 130:3, 130:11, 130:16, 130:18, 130:21, 131:3, 131:15, 132:11, 132:17, 133:19, 134:12, 134:15, 136:15, 138:4, 214:2 Plaintiffs [1] - 250:6 plaintiffs' [1] - 137:7 plan [2] - 127:20, 128:4 plane [1] - 24:7 plausible [3] - 129:22, 131:10, 236:5 play [1] - 148:17 Pleasant [3] - 3:15, 4:4, 4:9 pleasure [1] - 134:5 plus [4] - 130:7, 131:12, 204:22, 205:4 point [50] - 19:16, 19:17, 22:3, 23:14, 29:5, 31:18, 39:14, 41:10, 57:10, 57:13, 58:18, 63:14, 75:8, 95:13, 113:20, 119:23, 125:10, 126:3, 128:19, 131:3, 132:16, 134:3, 135:16, 137:2, 137:14, 149:5, 152:6, 165:12, 165:16, 166:21, 167:6, 184:7, 194:23, 195:2, 201:22,</p>	<p>207:8, 209:12, 228:6, 228:8, 228:19, 230:1, 230:6, 230:13, 239:9, 239:25, 242:19, 242:24, 243:7, 244:10, 244:18 pointer [2] - 103:16, 113:3 pointing [1] - 126:15 points [6] - 38:13, 74:7, 76:7, 155:16, 155:18, 242:11 police [1] - 211:14 policies [7] - 177:20, 182:8, 215:21, 215:22, 216:11, 216:12, 221:5 policy [8] - 19:24, 175:16, 175:17, 175:20, 182:10, 216:10, 216:11, 231:10 polite [1] - 229:24 Ponc [1] - 2:4 Ponce [1] - 2:16 population [9] - 120:6, 181:7, 185:7, 186:18, 186:19, 197:23, 199:14, 200:21 portion [4] - 40:8, 65:24, 126:6, 203:18 posed [2] - 93:22, 162:25 position [12] - 30:5, 66:13, 97:22, 98:13, 132:19, 167:4, 173:8, 187:20, 187:21, 189:12, 214:19, 241:11 positive [1] - 180:17 possible [5] - 123:14, 141:10, 171:3, 213:23, 234:3 possibly [2] - 104:21, 141:9 Post [2] - 208:16, 209:9 post [4] - 116:22, 153:20, 153:23, 153:24 posted [2] - 153:19, 155:6 potential [5] - 103:16, 162:22, 244:4, 244:10, 244:17 potentially [2] - 104:7, 117:19</p>	<p>powder [1] - 197:1 Powell [1] - 2:6 PR [2] - 2:5, 2:17 practical [1] - 193:11 practice [4] - 29:2, 37:1, 141:12, 153:20 practices [5] - 26:16, 36:24, 151:5, 152:1, 156:4 practitioners [5] - 117:15, 120:12, 121:7, 234:10, 234:19 pre [2] - 50:19, 66:14 pre-dates [2] - 50:19, 66:14 precise [1] - 224:13 precisely [1] - 17:5 prejudge [1] - 209:12 prejudiced [1] - 132:12 prejudices [1] - 127:19 prejudicial [1] - 166:8 prepared [2] - 128:5, 153:25 preparing [3] - 126:11, 243:4, 243:5 prescribe [2] - 121:8, 184:15 prescribed [1] - 199:8 prescriber [1] - 186:6 prescribers [12] - 22:8, 171:12, 171:16, 184:22, 184:24, 185:3, 185:5, 185:7, 185:10, 185:18, 185:19, 186:2 prescribing [13] - 21:9, 121:7, 163:24, 164:23, 164:24, 165:1, 165:7, 184:19, 184:22, 185:3, 185:10, 186:16 prescription [22] - 21:4, 21:15, 21:17, 22:10, 23:1, 23:2, 23:10, 24:20, 24:24, 25:6, 117:18, 163:15, 186:7, 193:13, 194:11, 195:24, 195:25, 196:5, 202:9, 202:12, 202:20 prescriptions [10] - 18:2, 21:10, 22:13, 25:2, 25:3, 25:12, 120:13, 199:11,</p>	<p>202:1, 202:14 present [7] - 26:22, 27:1, 99:3, 99:5, 129:13, 131:16, 180:13 presentation [14] - 153:10, 153:12, 154:23, 154:24, 154:25, 155:2, 155:5, 192:13, 192:15, 192:17, 192:19, 194:9, 194:15, 194:18 presentations [9] - 25:19, 25:20, 25:21, 26:23, 26:24, 152:17, 153:24, 154:18, 154:20 presented [10] - 13:4, 13:13, 14:16, 28:8, 28:16, 130:17, 131:11, 134:4, 155:2, 162:7 preserve [1] - 11:24 preserved [2] - 67:4, 79:22 preserving [1] - 225:8 press [2] - 9:1, 115:10 pretty [12] - 23:16, 88:20, 132:2, 134:9, 172:23, 173:1, 181:14, 215:12, 223:24, 229:18, 240:23, 245:7 prevent [5] - 117:14, 151:5, 167:10, 169:15, 204:5 previous [1] - 141:14 previously [9] - 39:9, 48:25, 67:12, 86:12, 97:2, 141:25, 152:16, 171:17, 244:19 Prevosnick [1] - 56:4 Prevosnik [1] - 55:25 Prevoznik [2] - 56:18, 56:19 Prevoznik's [1] - 167:8 printout [1] - 111:22 privilege [7] - 8:13, 8:15, 49:15, 49:21, 120:22, 120:23 privileged [6] - 8:8, 43:4, 49:19, 106:7, 120:22 probe [1] - 112:9 problem [17] - 8:23, 25:9, 27:24, 38:19, 49:23, 87:20,</p>	<p>125:22, 134:10, 146:24, 157:14, 164:1, 164:4, 194:19, 197:14, 201:7, 201:11, 202:2 problematic [1] - 61:8 problems [4] - 43:23, 60:5, 95:21, 164:19 procedure [1] - 182:10 procedures [11] - 96:20, 177:20, 178:5, 178:11, 179:9, 182:8, 220:24, 244:2, 244:8, 244:16, 244:20 proceed [6] - 41:4, 68:1, 88:25, 119:24, 165:20, 209:25 proceeded [1] - 38:4 proceeding [3] - 37:9, 87:23, 149:10 Proceedings [3] - 6:19, 67:25, 184:9 proceedings [1] - 250:5 PROCEEDINGS [1] - 7:1 process [21] - 8:15, 49:16, 120:23, 134:23, 135:8, 149:7, 157:19, 175:1, 175:4, 180:3, 180:15, 182:13, 218:12, 220:24, 221:1, 229:13, 229:14, 229:23, 241:5, 241:7 processed [1] - 178:8 processes [2] - 42:5, 178:11 Proctor [1] - 2:12 produced [1] - 6:19 products [5] - 18:14, 40:5, 89:21, 200:5, 247:24 program [6] - 54:2, 54:3, 58:16, 62:14, 62:24, 64:7 Program [3] - 18:17, 182:17, 230:17 Programs [3] - 50:13, 240:9, 240:13 programs [3] - 161:16, 166:20, 181:23 prohibited [1] - 41:11 promised [1] - 7:17 proof [1] - 122:18 proper [3] - 33:21, 112:15, 238:19</p>
--	--	--	--	--

<p>properly [1] - 150:21</p> <p>proportion [1] - 125:2</p> <p>proposal [2] - 133:16, 136:16</p> <p>propose [1] - 133:22</p> <p>proposed [4] - 136:12, 242:7, 246:6, 246:14</p> <p>proposing [4] - 130:3, 130:18, 133:19, 134:16</p> <p>proprietary [1] - 169:5</p> <p>protocol [1] - 112:23</p> <p>protocols [3] - 55:15, 178:5, 179:9</p> <p>prove [2] - 124:2, 124:25</p> <p>proven [1] - 71:13</p> <p>provide [22] - 27:20, 66:13, 74:13, 94:24, 110:21, 112:8, 115:18, 118:10, 140:9, 150:1, 152:3, 157:21, 168:9, 168:24, 172:19, 173:2, 183:22, 186:10, 215:1, 218:14, 235:2, 236:4</p> <p>provided [25] - 12:18, 26:23, 57:15, 57:16, 60:15, 67:3, 74:8, 75:17, 117:24, 121:20, 141:16, 152:11, 152:13, 152:17, 153:16, 154:1, 156:7, 173:5, 182:1, 191:15, 192:15, 211:5, 217:14, 217:16, 248:10</p> <p>providers [2] - 184:15, 184:19</p> <p>provides [3] - 58:10, 116:24, 196:20</p> <p>providing [5] - 22:9, 95:1, 145:5, 145:14, 243:20</p> <p>provision [8] - 49:5, 50:10, 57:24, 82:22, 172:5, 172:11, 198:24, 203:13</p> <p>provisions [4] - 83:13, 89:24, 139:25, 172:7</p> <p>proxy [1] - 34:18</p> <p>public [16] - 8:8, 8:12, 30:1, 35:1, 61:14, 61:16, 61:21, 81:14, 120:24, 141:3, 166:2, 166:5, 170:13, 188:8, 188:9, 188:18</p>	<p>publicly [3] - 49:17, 170:16, 205:22</p> <p>publish [1] - 198:18</p> <p>published [4] - 149:15, 149:18, 149:19, 149:20</p> <p>pull [5] - 16:1, 31:25, 59:7, 227:10, 232:16</p> <p>pulled [2] - 35:4, 232:18</p> <p>pulls [1] - 21:6</p> <p>Purchase [2] - 109:15, 145:10</p> <p>purchase [15] - 103:17, 103:18, 103:20, 104:3, 109:17, 112:2, 112:14, 113:7, 113:21, 114:24, 115:1, 213:22, 214:19, 214:22, 214:24</p> <p>purchased [3] - 161:22, 162:16, 163:6</p> <p>purchases [4] - 13:20, 104:12, 234:9, 234:18</p> <p>pure [7] - 19:1, 53:1, 54:21, 55:2, 169:16, 173:12, 195:13</p> <p>purported [2] - 53:5, 216:4</p> <p>purportedly [1] - 26:7</p> <p>purporting [2] - 101:3, 206:8</p> <p>purpose [10] - 11:4, 100:7, 116:13, 188:5, 193:4, 193:7, 194:7, 224:4, 224:5, 224:7</p> <p>purposes [6] - 48:7, 80:17, 116:9, 175:25, 197:19, 224:1</p> <p>pursuant [1] - 188:18</p> <p>pursue [1] - 172:24</p> <p>purview [3] - 30:25, 34:21, 56:1</p> <p>put [37] - 28:1, 58:19, 60:2, 95:6, 96:23, 101:9, 113:16, 124:5, 124:14, 125:8, 126:7, 127:15, 129:22, 129:25, 131:4, 132:17, 132:25, 135:20, 147:21, 150:6, 156:10, 159:7, 173:9,</p>	<p>175:23, 190:9, 192:1, 193:21, 198:3, 200:25, 203:2, 222:6, 226:8, 226:14, 233:16, 236:25, 240:23</p> <p>putting [10] - 54:2, 123:17, 124:7, 125:15, 135:7, 149:24, 166:10, 167:18, 190:1</p>	<p>198:19, 199:2, 199:6, 199:9, 199:10, 199:13, 199:20, 199:21, 199:22, 200:7, 200:8, 200:17, 201:14, 201:15, 202:21, 202:24, 203:6, 203:8, 203:10, 203:13, 203:15, 203:19, 204:4</p> <p>Quota [1] - 200:10</p> <p>quote [2] - 35:1, 238:9</p>	<p>114:10, 114:14, 115:13, 116:15, 121:13, 121:14, 121:15, 123:14, 138:13, 138:22, 138:25, 139:5, 141:15, 141:22, 142:20, 142:22, 143:6, 143:19, 144:18, 146:12, 146:23, 147:12, 147:22, 148:7, 152:16, 153:6, 154:13, 155:15, 156:11, 158:15, 160:3, 161:13, 161:25, 162:14, 164:22, 166:11, 166:14, 167:11, 170:23, 171:19, 172:2, 173:20, 175:13, 176:12, 178:22, 184:12, 187:8, 188:25, 190:5, 190:12, 192:9, 192:10, 195:8, 195:14, 195:22, 196:13, 198:4, 200:6, 203:6, 204:16, 205:18, 206:14, 207:1, 209:24, 233:20, 249:1</p> <p>Rannazzisi's [6] - 11:19, 12:20, 73:21, 73:23, 74:9, 98:12</p> <p>rather [13] - 11:22, 14:2, 35:4, 88:24, 93:15, 130:12, 132:18, 143:14, 145:2, 147:17, 203:11, 217:2, 221:22</p> <p>rationale [1] - 131:1</p> <p>raw [2] - 157:14, 158:9</p> <p>razor [1] - 57:4</p> <p>re [9] - 18:7, 20:14, 39:3, 39:5, 41:17, 123:16, 144:5, 148:14, 148:15</p> <p>re-evaluate [1] - 123:16</p> <p>re-packaged [1] - 148:15</p> <p>re-packager [1] - 148:14</p> <p>re-sent [1] - 144:5</p> <p>re-state [3] - 18:7, 39:3, 39:5</p> <p>re-tread [1] - 20:14</p>
Q				
<p>qualification [1] - 105:16</p> <p>Quantico [1] - 139:13</p> <p>quantify [1] - 220:25</p> <p>quantities [12] - 13:18, 14:19, 16:9, 17:9, 25:8, 36:23, 84:7, 89:14, 145:20, 145:22, 168:14</p> <p>quantity [1] - 157:23</p> <p>quarter [1] - 159:20</p> <p>quarterly [1] - 156:24</p> <p>questioned [5] - 74:1, 74:16, 74:19, 74:21, 75:24</p> <p>questioning [5] - 73:20, 74:4, 79:22, 166:7, 186:16</p> <p>questionnaire [2] - 21:2, 21:14</p> <p>questionnaires [2] - 20:24, 21:1</p> <p>questions [12] - 8:22, 8:23, 90:15, 115:5, 121:2, 128:23, 146:19, 186:23, 195:4, 210:19, 229:19, 239:6</p> <p>quick [1] - 242:11</p> <p>quicker [1] - 135:21</p> <p>quickly [2] - 33:24, 144:12</p> <p>quite [7] - 41:9, 130:25, 133:14, 134:15, 179:15, 185:23, 203:4</p> <p>quitting [1] - 136:19</p> <p>quota [42] - 196:14, 196:17, 196:18, 196:22, 196:25, 197:4, 197:13, 197:14, 197:20, 197:21, 197:23, 197:25, 198:7, 198:8, 198:10, 198:13, 198:17,</p>				
R				
<p>Rader [1] - 126:3</p> <p>radically [1] - 131:7</p> <p>Rafferty [1] - 2:12</p> <p>raise [2] - 115:6, 186:4</p> <p>raised [6] - 91:5, 114:7, 114:10, 169:4, 217:7</p> <p>raising [1] - 221:6</p> <p>range [2] - 121:6, 124:10</p> <p>Rannazzisi [157] - 7:10, 7:16, 9:3, 10:7, 10:23, 12:4, 13:1, 13:11, 14:3, 15:3, 15:8, 16:4, 19:13, 23:7, 27:9, 27:19, 28:10, 32:4, 33:3, 36:1, 36:11, 38:17, 39:22, 41:6, 41:24, 42:16, 43:16, 44:8, 46:16, 46:24, 49:21, 50:8, 51:2, 51:18, 52:1, 52:12, 52:13, 54:16, 54:24, 56:2, 56:8, 56:9, 56:13, 57:9, 57:25, 58:13, 59:11, 63:18, 65:16, 65:22, 66:8, 67:8, 67:22, 68:4, 68:8, 70:1, 70:21, 72:6, 72:23, 73:8, 74:1, 74:15, 74:25, 75:24, 76:20, 77:1, 79:7, 80:1, 84:21, 86:2, 86:19, 88:3, 92:15, 92:25, 93:13, 94:8, 96:25, 98:13, 98:24, 101:9, 101:23, 102:11, 103:10, 105:16, 107:9, 107:21, 108:14, 109:2, 109:13, 111:16, 112:17,</p>				

<p>reach [2] - 31:18, 79:11</p> <p>reached [2] - 50:1, 65:19</p> <p>reaction [1] - 229:22</p> <p>read [31] - 14:24, 16:5, 36:18, 47:14, 48:5, 48:22, 58:8, 60:14, 65:21, 65:24, 68:22, 80:15, 89:12, 90:13, 90:17, 93:13, 93:18, 93:19, 117:11, 118:3, 118:14, 120:9, 140:7, 148:20, 149:3, 151:14, 151:24, 213:16, 222:21</p> <p>reading [7] - 81:6, 92:15, 93:15, 98:18, 145:3, 190:13, 238:16</p> <p>real [3] - 134:10, 228:19, 235:17</p> <p>real-time [1] - 235:17</p> <p>realized [1] - 239:24</p> <p>really [14] - 17:16, 20:22, 22:9, 27:6, 55:1, 123:19, 125:20, 127:5, 129:7, 130:4, 132:12, 137:24, 245:13, 245:15</p> <p>reason [15] - 17:4, 18:4, 19:13, 51:25, 63:20, 66:2, 103:13, 130:21, 135:17, 141:1, 147:16, 175:15, 197:6, 204:24, 225:2</p> <p>reasonable [1] - 141:8</p> <p>reasons [7] - 11:18, 72:3, 136:20, 146:1, 153:22, 156:3, 175:13</p> <p>rebutting [1] - 127:22</p> <p>receive [7] - 110:6, 110:10, 146:15, 156:18, 156:21, 191:6, 191:7</p> <p>received [10] - 16:8, 104:2, 107:18, 108:17, 112:1, 112:13, 123:5, 141:24, 227:22, 247:8</p> <p>receives [2] - 157:12, 158:1</p> <p>receiving [3] - 21:10, 104:9, 109:17</p> <p>recent [1] - 220:9</p>	<p>recess [3] - 67:20, 122:4, 249:4</p> <p>Recess [3] - 67:24, 122:6, 184:8</p> <p>recessed [2] - 102:13, 249:6</p> <p>recipient [1] - 223:17</p> <p>recites [1] - 98:6</p> <p>recognize [46] - 10:7, 10:10, 32:4, 32:7, 44:8, 44:10, 68:8, 68:10, 72:23, 73:11, 73:13, 77:7, 77:10, 78:7, 78:9, 80:3, 81:2, 86:2, 86:4, 109:2, 109:13, 116:19, 139:6, 139:9, 142:2, 142:4, 143:20, 143:22, 144:18, 148:7, 150:7, 153:9, 154:13, 154:17, 154:23, 172:13, 187:8, 187:11, 188:25, 189:2, 192:11, 192:14, 229:23, 247:17, 247:21</p> <p>recognized [1] - 88:4</p> <p>recognizes [1] - 117:12</p> <p>recollection [10] - 13:7, 15:4, 42:25, 91:16, 92:9, 92:19, 93:1, 93:14, 94:9, 114:1</p> <p>recommend [4] - 32:10, 59:21, 86:7, 89:5</p> <p>recommendations [5] - 30:18, 30:21, 30:22, 31:2, 198:20</p> <p>recommended [1] - 31:19</p> <p>recommending [2] - 29:12, 31:5</p> <p>record [20] - 8:18, 32:8, 35:1, 41:13, 56:3, 67:4, 67:6, 75:12, 93:16, 105:6, 113:25, 116:9, 188:8, 188:9, 188:11, 188:18, 190:1, 223:25, 225:9, 250:5</p> <p>recorded [1] - 6:19</p> <p>recording [1] - 223:25</p> <p>recordkeeping [1] - 179:17</p> <p>records [5] - 86:25,</p>	<p>173:3, 173:10, 173:22, 173:24</p> <p>recount [3] - 13:2, 14:6, 15:11</p> <p>recounts [1] - 98:11</p> <p>red [5] - 14:21, 121:5, 121:11, 151:9, 161:1</p> <p>redacted [1] - 16:12</p> <p>reduce [3] - 201:16, 201:17</p> <p>reduced [1] - 202:15</p> <p>Reed [2] - 6:4, 6:11</p> <p>refer [3] - 69:2, 149:7, 214:18</p> <p>reference [9] - 139:14, 222:11, 226:12, 227:18, 235:10, 243:11, 243:17, 248:5, 248:9</p> <p>referenced [3] - 40:13, 75:3, 75:22</p> <p>references [2] - 74:14, 239:8</p> <p>referencing [2] - 220:15, 221:23</p> <p>referred [4] - 40:11, 143:10, 147:23, 161:25</p> <p>referring [3] - 31:21, 32:18, 143:11</p> <p>refills [3] - 202:9, 202:11, 202:19</p> <p>reflect [13] - 70:9, 79:2, 90:1, 90:14, 117:24, 121:15, 141:16, 151:3, 155:19, 155:20, 156:7, 187:23, 191:14</p> <p>reflects [1] - 11:8</p> <p>refresh [5] - 91:15, 92:9, 92:19, 93:1, 94:9</p> <p>refreshes [1] - 93:14</p> <p>regard [5] - 11:20, 43:1, 43:6, 53:25, 89:1</p> <p>regarding [7] - 170:13, 173:3, 200:5, 219:7, 244:15, 248:10</p> <p>regardless [1] - 168:12</p> <p>Register [4] - 149:21, 149:24, 150:10</p> <p>register [2] - 119:12, 210:13</p> <p>registered [9] - 117:13, 140:11, 184:16, 217:1,</p>	<p>217:5, 218:2, 225:25, 227:7, 228:2</p> <p>registrant [7] - 28:18, 113:1, 119:1, 119:21, 141:11, 156:24, 169:8</p> <p>registrants [23] - 25:16, 115:21, 117:14, 117:25, 139:21, 140:24, 140:25, 141:13, 141:14, 141:20, 143:23, 144:4, 145:23, 150:1, 150:4, 153:17, 156:3, 156:7, 157:3, 173:2, 176:21, 176:23, 205:11</p> <p>registrants' [1] - 116:3</p> <p>Registration [1] - 59:13</p> <p>registration [18] - 28:21, 28:22, 30:4, 37:13, 37:14, 37:18, 37:23, 117:20, 118:12, 119:11, 140:10, 148:11, 150:8, 185:18, 210:16, 230:7, 230:9, 236:22</p> <p>registrations [2] - 117:23, 119:10</p> <p>regularly [3] - 38:5, 212:20, 214:12</p> <p>regulate [1] - 205:10</p> <p>regulated [1] - 100:24</p> <p>regulation [3] - 147:19, 172:15, 172:18</p> <p>Regulations [2] - 179:21, 179:23</p> <p>regulations [1] - 141:10</p> <p>regulator [2] - 100:23, 205:10</p> <p>regulators [4] - 152:25, 207:25, 208:1</p> <p>regulatory [5] - 145:11, 212:24, 213:2, 213:13, 234:2</p> <p>reinforces [1] - 116:23</p> <p>reiterate [2] - 116:2, 147:20</p> <p>relate [2] - 78:1, 78:11</p> <p>related [4] - 31:3, 43:1, 76:4, 140:10</p> <p>relates [3] - 11:15, 88:16, 211:22</p> <p>relating [1] - 116:25</p>	<p>relationship [6] - 20:20, 195:12, 205:7, 205:9, 205:10, 205:20</p> <p>release [1] - 43:3</p> <p>Release [3] - 44:11, 68:11, 80:4</p> <p>relevance [6] - 17:19, 26:13, 146:21, 208:17, 208:18, 209:5</p> <p>Relevant [1] - 223:16</p> <p>relevant [4] - 17:20, 163:1, 166:19, 211:21</p> <p>rely [4] - 42:21, 118:24, 119:9, 145:16</p> <p>remained [8] - 218:1, 218:17, 225:17, 225:24, 227:7, 228:2, 228:9</p> <p>remaining [3] - 122:22, 125:12, 137:12</p> <p>remarks [1] - 187:23</p> <p>remember [32] - 65:18, 79:13, 87:6, 87:7, 107:11, 121:2, 147:22, 149:17, 170:4, 187:3, 212:8, 213:7, 219:5, 219:18, 224:11, 225:21, 228:6, 230:14, 232:4, 232:17, 232:18, 237:10, 237:11, 237:15, 239:12, 241:4, 243:24, 244:22, 244:24, 245:4</p> <p>remind [1] - 204:16</p> <p>removed [1] - 93:11</p> <p>removing [1] - 125:21</p> <p>renew [1] - 63:5</p> <p>repeat [15] - 13:25, 14:2, 20:5, 45:18, 50:9, 62:18, 66:23, 70:16, 90:10, 180:25, 203:9, 204:1, 217:3, 221:18, 244:12</p> <p>repeatedly [1] - 151:16</p> <p>rephrase [2] - 22:25, 196:1</p> <p>report [26] - 48:16, 49:1, 49:3, 64:16, 69:14, 81:9, 82:20, 89:21, 100:5,</p>
---	---	---	---	--

<p>103:24, 108:3, 109:4, 109:7, 110:1, 110:2, 112:20, 140:4, 140:24, 140:25, 145:9, 156:23, 156:25, 157:9, 158:21, 160:14, 239:20 Report [6] - 107:22, 108:4, 108:17, 109:15, 145:10, 157:11 reportable [1] - 69:12 reported [3] - 156:22, 158:24, 250:9 Reporter [6] - 6:17, 6:18, 250:3, 250:12 REPORTER [7] - 8:10, 10:19, 27:10, 27:12, 40:21, 49:12, 71:20 reporter [2] - 65:21, 65:24 reporting [15] - 79:9, 84:9, 102:17, 103:11, 111:18, 114:8, 116:6, 118:5, 141:11, 145:15, 160:18, 172:11, 198:8, 215:2, 239:24 reports [40] - 36:20, 40:17, 103:17, 103:18, 103:20, 109:17, 110:6, 110:8, 110:21, 111:11, 112:1, 112:2, 112:3, 112:13, 112:14, 112:19, 112:23, 112:25, 113:2, 113:7, 113:21, 114:24, 115:2, 118:16, 128:3, 133:3, 133:4, 213:22, 214:22, 214:24, 243:11, 243:12, 243:17, 243:21, 243:25, 244:23, 245:4, 247:8 Reports [2] - 69:12, 173:25 represen [1] - 83:15 represent [4] - 33:19, 55:19, 155:16, 189:15 representative [5] - 99:13, 187:15, 187:17, 189:8, 189:9 Representatives [1] - 233:10 representatives [2] -</p>	<p>237:3, 237:5 represented [3] - 61:14, 61:21, 81:14 representing [1] - 187:17 represents [1] - 193:10 request [7] - 17:6, 37:3, 122:10, 131:5, 140:21, 159:23, 198:13 requested [4] - 8:4, 13:17, 65:24, 198:12 requests [1] - 198:10 require [4] - 82:15, 82:19, 82:20, 157:8 required [13] - 48:17, 69:16, 81:10, 83:1, 83:9, 89:22, 95:1, 118:16, 186:15, 197:5, 198:1, 202:17, 235:2 requirement [8] - 82:17, 82:18, 118:22, 140:4, 145:9, 145:11, 157:1, 159:6 requirements [2] - 145:24, 146:7 requires [2] - 119:6, 201:13 requiring [1] - 235:11 rescind [1] - 54:24 rescinded [1] - 49:1 research [9] - 197:17, 197:24, 199:16, 199:19, 199:23, 199:25, 200:3, 200:4 researchers [1] - 199:18 reservation [1] - 75:21 reservations [1] - 83:20 reserve [1] - 137:6 reserved [1] - 74:25 resolve [3] - 80:7, 104:1, 121:10 resolved [3] - 71:10, 96:13, 178:8 resolving [3] - 69:22, 70:3, 152:9 resource [1] - 41:7 resources [10] - 22:17, 23:8, 23:11, 23:12, 41:6, 41:23, 43:17, 43:19, 171:6, 210:19 respect [17] - 21:24, 31:2, 47:3, 49:2, 56:17, 69:11, 70:10,</p>	<p>74:23, 76:8, 78:22, 96:21, 122:24, 127:25, 130:2, 195:11, 198:6, 205:19 respectfully [1] - 164:14 respond [2] - 171:4, 193:8 responded [2] - 17:5, 18:6 respondent [4] - 60:15, 60:21, 151:15, 227:19 respondents [1] - 151:19 response [8] - 33:7, 55:6, 120:5, 146:15, 220:9, 233:15, 233:19, 236:9 responsibilities [3] - 31:15, 116:3, 147:20 responsibility [7] - 29:16, 102:1, 117:8, 117:16, 118:6, 140:19, 176:22 responsible [2] - 28:23, 29:12 rest [2] - 128:21, 138:6 restate [1] - 114:9 restricted [1] - 76:13 rests [1] - 140:20 result [3] - 196:4, 215:22, 240:9 results [2] - 10:11, 10:12 resume [2] - 7:10, 138:21 resumed [2] - 67:25, 184:9 retail [6] - 89:15, 89:19, 171:5, 171:11, 234:9, 234:18 retrieve [1] - 94:5 retrieved [1] - 16:6 retrospective [1] - 235:15 retrospectively [4] - 170:1, 170:3, 217:10, 234:22 return [1] - 102:11 reveal [3] - 8:16, 166:13, 191:5 revealed [3] - 16:7, 167:6, 191:11 review [25] - 8:4, 9:4, 9:11, 13:20, 21:14, 29:16, 29:18, 53:6, 53:9, 57:19, 58:11,</p>	<p>59:25, 68:15, 84:9, 148:23, 161:19, 177:19, 178:5, 179:9, 213:21, 214:18, 214:24, 221:1, 246:2, 246:4 reviewed [15] - 30:11, 36:20, 53:10, 57:20, 59:24, 60:5, 81:19, 89:7, 94:8, 230:22, 231:6, 242:18, 243:8, 244:7, 248:18 reviewing [1] - 95:22 reviews [1] - 58:3 revising [1] - 220:24 revocation [7] - 37:13, 37:14, 37:22, 118:11, 148:10, 148:17, 149:9 revoke [2] - 117:22, 185:17 revoked [1] - 119:11 revoking [1] - 150:8 Reynolds [1] - 226:17 Rice [5] - 2:9, 3:14, 4:3, 4:5, 4:8 rigid [1] - 145:16 ring [1] - 175:12 rise [1] - 33:18 rising [1] - 33:17 RMR [2] - 6:17, 6:18 road [8] - 7:17, 7:18, 119:14, 156:12, 196:20, 198:2, 204:15 roads [1] - 24:14 ROBERT [1] - 6:11 ROBERTSON [1] - 3:6 rogue [6] - 22:5, 22:6, 22:7, 22:14, 191:7, 191:12 role [12] - 50:19, 53:12, 56:1, 66:15, 148:17, 148:19, 156:16, 198:5, 198:19, 211:20, 212:6, 212:20 roles [1] - 137:16 room [1] - 162:4 roughly [5] - 91:12, 123:10, 123:11, 135:10, 135:11 Roughly [1] - 110:1 routinely [2] - 140:24, 140:25 RPR [1] - 6:18 RPR-RMR-CRR- FCRR [1] - 6:18 Ruby [1] - 4:17 RUBY [1] - 4:17</p>	<p>rule [3] - 34:1, 147:17, 172:24 ruled [2] - 34:8, 73:23 Rules [1] - 127:4 ruling [3] - 34:9, 34:22, 76:16 rulings [1] - 123:5 run [7] - 23:16, 130:12, 131:5, 131:6, 211:15, 239:11 running [3] - 11:25, 136:2, 170:21 runs [1] - 194:18 Ryan [3] - 22:1, 215:14, 215:18</p>
S				
<p>sAyme [1] - 250:11 sLisa [1] - 250:11 sacrifice [1] - 127:18 sad [1] - 66:25 safeguards [1] - 117:16 safety [5] - 30:1, 61:14, 61:21, 81:14, 141:4 salary [1] - 208:9 sale [1] - 235:3 sales [17] - 8:5, 22:3, 47:9, 47:20, 69:11, 69:15, 163:15, 220:20, 220:25, 222:2, 222:19, 226:19, 227:2, 227:18, 232:11, 236:5, 248:10 SALGADO [1] - 4:15 San [2] - 2:5, 2:17 sand [1] - 136:4 Sanford [1] - 95:9 satisfactorily [1] - 182:14 satisfactory [2] - 58:15, 182:15 saw [6] - 22:1, 25:7, 33:18, 43:25, 129:11, 242:4 SC [3] - 3:15, 4:4, 4:9 scale [2] - 31:11, 191:22 Schedule [16] - 159:1, 159:2, 159:3, 159:9, 159:10, 159:11, 159:12, 202:5, 202:6, 202:8, 202:10, 247:17, 247:21 schedule [3] - 122:21,</p>				

<p>123:9, 202:5 scheduled [1] - 123:9 Schmidt [11] - 11:13, 35:7, 38:14, 42:7, 50:5, 53:24, 56:21, 100:9, 209:21, 219:10, 238:21 SCHMIDT [129] - 5:9, 11:14, 11:24, 12:2, 12:13, 13:5, 14:10, 14:22, 17:19, 18:25, 19:6, 19:22, 27:23, 33:4, 33:14, 35:8, 35:12, 38:3, 38:21, 40:8, 40:13, 40:19, 40:22, 41:14, 42:8, 46:12, 46:21, 49:20, 50:15, 50:19, 50:21, 51:9, 51:15, 52:2, 53:1, 53:5, 54:20, 56:6, 56:22, 57:18, 83:3, 98:16, 99:16, 99:21, 99:24, 100:10, 101:1, 101:14, 102:3, 102:19, 102:22, 104:17, 104:19, 105:5, 105:21, 106:11, 106:22, 107:6, 109:19, 111:12, 112:11, 113:9, 114:3, 145:25, 146:20, 150:15, 150:19, 155:10, 162:6, 163:25, 165:11, 166:21, 169:16, 173:12, 175:8, 178:16, 183:18, 189:24, 190:3, 191:19, 193:1, 194:2, 194:4, 194:13, 195:13, 196:8, 203:22, 205:13, 206:7, 206:10, 207:5, 208:17, 208:22, 209:23, 209:25, 210:3, 213:4, 213:6, 214:4, 214:7, 214:11, 214:16, 214:17, 218:6, 218:9, 219:1, 219:3, 219:4, 219:12, 219:15, 219:17, 223:12, 223:16, 223:19, 223:24, 224:9, 224:20, 224:22, 225:7, 225:14, 229:17, 229:22, 229:25,</p>	<p>238:22, 241:21, 241:25, 248:21, 248:24, 249:5 Schmidt's [1] - 54:5 school [1] - 205:2 scientific [9] - 47:9, 47:20, 118:8, 197:8, 197:19, 197:25, 200:4, 200:10, 203:17 scientists [2] - 198:9 scope [21] - 11:14, 42:17, 42:20, 73:21, 73:24, 75:2, 75:4, 75:17, 76:8, 76:9, 76:14, 76:17, 88:16, 88:19, 88:23, 90:21, 101:25, 195:16, 195:18, 196:8, 203:22 score [1] - 55:19 screen [11] - 47:11, 143:7, 143:19, 100:9, 190:12, 193:21, 193:25, 233:16, 240:24, 245:22, 248:13 search [1] - 217:21 seasonal [1] - 247:13 SEC [2] - 188:14, 188:17 second [39] - 15:13, 16:1, 16:5, 40:1, 44:25, 50:15, 50:16, 54:5, 57:9, 60:17, 69:1, 76:11, 80:25, 96:3, 116:15, 117:6, 117:9, 117:10, 117:11, 140:7, 140:14, 141:22, 145:13, 190:17, 193:4, 197:6, 197:23, 212:13, 220:17, 220:18, 221:9, 222:15, 225:2, 225:3, 235:25, 237:2, 239:5 Section [8] - 11:3, 15:17, 118:22, 119:6, 141:4, 230:18, 230:19, 231:11 section [3] - 16:6, 141:5, 198:19 sections [2] - 93:18 secure [1] - 180:1 Security [1] - 187:13 security [6] - 172:5, 172:7, 179:18, 179:19, 179:24</p>	<p>see [96] - 7:23, 16:11, 16:21, 25:13, 47:11, 50:2, 60:11, 65:12, 95:4, 104:21, 106:3, 106:9, 107:5, 108:20, 110:20, 124:12, 124:15, 124:23, 130:14, 131:9, 133:23, 134:11, 135:14, 135:25, 137:22, 139:16, 140:4, 167:24, 174:3, 174:5, 178:6, 179:10, 180:5, 186:20, 195:5, 198:4, 199:21, 209:11, 213:12, 213:15, 213:23, 220:6, 220:8, 220:12, 220:18, 221:2, 221:12, 221:24, 222:4, 222:10, 222:13, 223:5, 224:23, 224:25, 225:4, 225:5, 225:18, 226:12, 226:18, 226:25, 227:5, 227:12, 227:13, 227:18, 229:10, 231:25, 233:15, 233:19, 233:20, 233:22, 234:5, 234:13, 236:6, 237:3, 237:5, 237:9, 237:16, 242:4, 242:8, 242:14, 243:10, 243:13, 243:17, 244:5, 245:17, 245:20, 245:25, 246:5, 246:15, 246:21, 247:1, 247:11, 247:24, 248:5, 248:8, 248:16 seeing [11] - 22:4, 23:10, 25:8, 25:10, 25:17, 142:13, 169:25, 170:11, 171:5, 204:25 seek [3] - 37:2, 37:13, 39:12 seekers [7] - 200:14, 200:22, 203:1, 203:7, 203:12, 203:21, 204:6 seeking [9] - 21:7, 37:6, 37:8, 37:22, 54:12, 200:24,</p>	<p>201:18, 204:11 seem [2] - 187:3, 232:17 sell [5] - 60:25, 151:19, 151:23, 159:5, 160:12 selling [4] - 61:7, 151:17, 170:10, 238:10 seminar [1] - 127:3 send [5] - 20:25, 115:20, 116:1, 144:1, 144:22 sending [1] - 104:8 senior [2] - 12:8, 84:22 SENIOR [1] - 1:17 Senior [1] - 7:2 Sensabaugh [1] - 5:14 sense [2] - 40:5, 210:12 sensible [3] - 129:14, 129:15, 133:17 sensitive [9] - 8:16, 41:22, 42:3, 43:3, 49:17, 167:22, 170:15, 174:11, 174:18 sent [17] - 15:2, 21:15, 29:20, 43:8, 59:25, 89:9, 116:2, 117:2, 117:3, 144:5, 144:24, 146:16, 147:16, 147:19, 148:22, 245:1, 245:3 sentence [7] - 58:8, 60:14, 117:10, 118:15, 140:7, 140:14, 140:18 sentences [1] - 220:23 September [6] - 80:22, 81:11, 116:18, 144:2, 144:3, 144:5 series [1] - 115:21 serious [9] - 69:21, 70:5, 70:14, 70:18, 70:22, 70:25, 71:10, 72:1 seriously [1] - 245:7 serve [5] - 53:10, 53:18, 204:17, 204:25, 205:3 served [1] - 97:21 service [1] - 195:9 set [11] - 39:16, 39:17, 69:15, 88:8, 96:5, 125:9, 141:4, 157:1, 186:23, 188:12, 198:1 sets [3] - 32:23, 35:1,</p>	<p>188:9 setting [4] - 22:9, 129:13, 183:16, 198:7 settings [1] - 181:24 settle [1] - 157:10 Settlement [31] - 44:11, 44:14, 44:23, 45:24, 51:3, 58:6, 58:7, 58:19, 68:11, 69:22, 70:2, 71:9, 79:14, 80:4, 80:5, 80:7, 80:12, 81:3, 82:9, 82:14, 82:19, 82:25, 83:8, 83:13, 83:21, 83:25, 96:3, 96:12, 96:16, 96:19, 216:3 settlement [3] - 157:7, 157:11, 182:25 setup [1] - 100:14 seven [3] - 36:22, 37:1, 245:19 several [4] - 47:22, 95:8, 151:21, 240:12 shall [5] - 7:7, 48:8, 58:11, 68:24, 80:18 SHANNON [1] - 6:3 share [3] - 117:16, 120:13, 175:13 shared [4] - 139:20, 139:24, 139:25, 140:1 sharing [1] - 169:5 sheer [2] - 190:16, 190:18 shelf [1] - 201:10 shift [1] - 25:7 shifting [1] - 28:10 ship [10] - 13:14, 13:18, 39:20, 82:21, 104:1, 140:19, 152:4, 152:8, 152:9, 158:22 shipment [3] - 14:7, 104:11, 116:6 shipments [9] - 140:17, 141:12, 159:14, 169:11, 169:25, 170:5, 215:8, 215:15, 215:18 shipped [10] - 16:23, 103:21, 103:22, 103:24, 104:13, 168:21, 180:1, 180:2, 227:6 shipping [14] - 13:17, 17:8, 19:20, 84:10, 104:12, 104:14,</p>
--	---	---	--	---

<p>105:3, 105:19, 105:25, 107:3, 107:15, 107:17, 175:3</p> <p>ships [1] - 21:6</p> <p>shoes [1] - 34:16</p> <p>short [4] - 76:23, 123:23, 124:7, 133:5</p> <p>shortage [1] - 201:20</p> <p>shortages [3] - 180:5, 197:12, 200:23</p> <p>shortly [1] - 31:20</p> <p>shot [1] - 138:11</p> <p>show [25] - 14:24, 28:17, 28:20, 51:19, 68:4, 86:25, 87:4, 87:13, 101:15, 127:8, 149:12, 163:12, 163:14, 163:16, 165:12, 166:18, 168:20, 187:4, 188:23, 192:2, 208:14, 214:1, 218:23, 224:18, 240:24</p> <p>Show [106] - 28:15, 28:16, 28:25, 29:4, 29:15, 29:16, 29:17, 29:19, 30:11, 30:21, 31:2, 31:5, 31:9, 31:10, 31:12, 31:19, 32:9, 32:10, 32:16, 32:18, 32:20, 33:2, 35:16, 35:18, 36:12, 36:18, 37:2, 37:7, 37:12, 37:17, 37:25, 39:9, 39:12, 41:8, 43:18, 43:25, 46:1, 46:7, 46:13, 46:18, 58:21, 58:24, 58:25, 59:2, 59:4, 59:12, 59:16, 59:22, 59:24, 60:6, 61:7, 61:10, 63:3, 63:21, 65:17, 66:2, 67:9, 69:3, 71:18, 71:19, 71:23, 71:24, 71:25, 73:14, 73:16, 76:1, 77:3, 77:7, 77:11, 77:16, 77:23, 78:3, 78:10, 78:13, 78:20, 80:8, 80:19, 81:18, 81:25, 82:5, 82:9, 86:5, 88:5, 89:3, 89:5, 89:8, 89:12, 91:5, 91:21, 92:5, 93:3, 94:11, 95:7, 95:8, 96:13, 115:16, 148:21, 171:1, 185:24, 206:2,</p>	<p>206:3, 240:20, 241:11, 245:20</p> <p>showed [4] - 13:14, 107:21, 168:19, 224:11</p> <p>shower [1] - 192:8</p> <p>showing [1] - 13:16</p> <p>shown [8] - 32:5, 67:6, 98:1, 109:3, 178:20, 182:15, 187:9, 214:10</p> <p>shows [1] - 204:10</p> <p>shuffled [1] - 17:10</p> <p>shut [10] - 22:2, 204:13, 215:12, 218:12, 218:16, 228:18, 228:22, 228:24, 229:16, 234:3</p> <p>sic [1] - 44:16</p> <p>side [9] - 34:15, 74:3, 122:25, 126:6, 126:23, 128:25, 129:5, 129:10, 129:12</p> <p>sides [1] - 241:7</p> <p>sign [9] - 21:14, 29:17, 29:22, 46:6, 72:13, 78:21, 144:22, 198:16</p> <p>signature [2] - 32:15, 78:17</p> <p>signatures [1] - 83:21</p> <p>signed [6] - 33:3, 61:22, 78:19, 78:20, 142:9, 143:24</p> <p>significant [2] - 23:14, 31:10</p> <p>significantly [2] - 190:20, 199:3</p> <p>signing [1] - 78:15</p> <p>signs [2] - 120:15, 121:2</p> <p>similar [3] - 11:18, 118:20, 118:22</p> <p>simply [7] - 33:5, 54:11, 76:12, 118:24, 129:22, 165:16, 173:9</p> <p>SING [1] - 66:25</p> <p>Singer [23] - 27:15, 70:14, 71:7, 71:17, 74:6, 75:10, 75:12, 86:8, 87:21, 93:9, 94:6, 98:22, 100:3, 101:6, 103:4, 106:19, 108:6, 122:2, 143:10, 146:10, 184:10, 196:10, 207:8</p>	<p>singer [21] - 7:6, 14:14, 26:20, 33:18, 34:12, 34:23, 36:9, 41:19, 43:14, 46:25, 55:20, 57:6, 66:20, 138:13, 142:11, 142:25, 143:12, 146:6, 161:10, 162:1, 171:23</p> <p>SINGER [273] - 4:5, 7:7, 7:15, 9:2, 10:3, 10:6, 10:17, 10:20, 10:21, 11:11, 12:3, 12:17, 12:25, 13:9, 13:10, 15:3, 15:7, 16:1, 16:3, 17:21, 18:5, 19:7, 19:12, 20:2, 20:6, 22:24, 23:3, 23:6, 26:11, 26:21, 27:8, 27:11, 27:14, 27:16, 27:18, 28:2, 28:9, 31:25, 32:3, 33:1, 34:13, 34:24, 34:25, 35:5, 35:15, 36:10, 38:9, 38:11, 38:13, 39:2, 40:18, 40:24, 41:5, 41:16, 41:20, 42:18, 43:15, 44:5, 44:7, 46:15, 46:23, 47:1, 47:2, 50:5, 50:7, 50:18, 50:25, 51:1, 51:17, 51:21, 51:23, 52:10, 52:11, 54:7, 54:15, 56:9, 57:7, 57:8, 57:22, 59:7, 59:10, 62:7, 62:11, 62:20, 62:21, 63:2, 63:17, 64:4, 65:1, 65:10, 65:14, 65:15, 65:20, 65:25, 66:22, 67:7, 67:19, 68:1, 68:3, 68:5, 68:7, 69:25, 70:8, 70:15, 70:19, 70:20, 71:8, 72:5, 72:21, 72:22, 73:5, 73:7, 74:7, 75:7, 75:14, 76:25, 79:2, 79:6, 79:25, 81:23, 82:7, 83:14, 84:16, 84:18, 84:19, 85:11, 85:14, 85:17, 86:15, 87:4, 88:2, 88:11, 89:2, 90:12, 91:2, 92:11, 92:14, 92:23, 93:25, 94:7, 94:23, 96:1, 98:10, 98:23, 99:17, 99:22, 100:4, 100:21, 101:7, 101:8, 101:18, 102:9,</p>	<p>102:10, 103:5, 103:9, 104:18, 104:25, 105:12, 105:15, 107:12, 107:20, 108:8, 108:10, 108:13, 108:20, 108:23, 109:1, 109:10, 109:12, 109:24, 110:15, 111:5, 111:25, 112:24, 113:11, 113:14, 113:18, 113:19, 114:16, 114:22, 115:4, 115:11, 115:12, 116:8, 116:14, 121:12, 121:24, 122:3, 138:24, 139:3, 139:4, 142:16, 142:18, 143:1, 143:5, 143:14, 143:18, 146:4, 146:11, 147:2, 147:15, 148:3, 148:6, 150:12, 151:2, 153:3, 153:5, 154:3, 154:6, 154:10, 154:12, 155:8, 155:14, 156:1, 158:11, 158:14, 160:2, 160:7, 160:9, 161:11, 161:12, 162:13, 163:7, 164:21, 166:9, 167:7, 167:17, 169:23, 171:2, 171:24, 173:19, 174:24, 175:11, 176:4, 176:10, 176:11, 183:21, 184:5, 184:11, 185:16, 187:6, 187:7, 188:1, 188:7, 188:21, 189:18, 190:4, 190:9, 190:11, 191:25, 192:7, 193:9, 193:17, 193:20, 193:25, 194:8, 195:7, 195:21, 196:11, 196:12, 204:3, 205:17, 206:13, 206:25, 207:10, 208:20, 209:1, 209:14, 209:17, 209:19, 218:4, 219:9, 241:19</p> <p>Singer's [1] - 8:23</p> <p>single [5] - 19:15,</p>	<p>19:18, 191:13, 230:1, 230:2</p> <p>sit [3] - 178:6, 179:2, 201:10</p> <p>site [5] - 178:2, 230:21, 231:2, 231:4, 231:6</p> <p>situation [4] - 11:20, 26:15, 132:11, 165:22</p> <p>six [13] - 14:12, 123:9, 129:5, 129:10, 131:19, 131:22, 131:24, 137:7, 166:12, 221:14, 221:19, 221:23, 222:20</p> <p>six-week [1] - 129:10</p> <p>size [1] - 177:12</p> <p>skills [1] - 158:13</p> <p>Skinner [1] - 125:11</p> <p>skip [1] - 48:15</p> <p>Slide [4] - 155:15, 156:6, 171:25, 172:1</p> <p>slide [9] - 155:16, 155:18, 156:6, 156:8, 193:6, 193:9, 194:9, 194:17, 198:3</p> <p>slides [2] - 100:16, 100:17</p> <p>slower [1] - 126:8</p> <p>slows [1] - 126:13</p> <p>small [3] - 25:13, 151:12, 190:24</p> <p>smaller [1] - 25:13</p> <p>smile [3] - 17:11, 237:12, 237:22</p> <p>smiled [1] - 236:12</p> <p>smiling [1] - 236:24</p> <p>Smith [2] - 6:4, 6:11</p> <p>sold [1] - 60:21</p> <p>solely [1] - 30:25</p> <p>someone [7] - 102:4, 102:6, 193:5, 193:6, 194:15, 236:11, 236:23</p> <p>sometime [1] - 159:19</p> <p>sometimes [6] - 112:25, 211:11, 232:5, 232:24, 235:11, 245:5</p> <p>Sometimes [3] - 85:3, 245:5</p> <p>somewhere [5] - 21:5, 43:12, 119:14, 201:10, 211:17</p> <p>soon [1] - 176:2</p> <p>Sorry [2] - 92:24, 206:7</p> <p>sorry [93] - 8:11, 19:2,</p>
---	--	---	---	--

<p>22:18, 22:24, 27:4, 27:10, 27:11, 27:13, 27:14, 27:16, 31:1, 37:2, 38:11, 40:21, 44:6, 44:19, 44:22, 45:18, 47:1, 49:12, 49:13, 51:15, 51:24, 51:25, 52:23, 53:8, 58:14, 60:20, 61:3, 63:2, 64:21, 65:20, 66:7, 68:18, 70:15, 71:12, 71:20, 71:22, 72:24, 73:2, 73:4, 73:5, 73:15, 81:5, 84:13, 85:10, 85:14, 85:24, 86:10, 90:2, 90:14, 94:21, 96:9, 98:3, 103:5, 105:12, 108:5, 108:8, 108:10, 110:13, 118:19, 118:21, 137:1, 142:11, 145:7, 146:3, 150:18, 152:15, 155:17, 162:24, 164:8, 164:10, 168:19, 170:19, 172:6, 181:10, 185:4, 187:5, 190:16, 191:19, 192:19, 196:1, 198:5, 203:9, 211:9, 214:5, 222:22, 222:25, 226:16, 244:12, 245:21, 248:12</p> <p>sort [5] - 67:4, 106:19, 130:11, 212:24, 213:13</p> <p>sorting [1] - 87:24</p> <p>sorts [1] - 121:7</p> <p>sounds [2] - 42:10, 173:15</p> <p>sources [3] - 54:25, 191:11, 191:17</p> <p>South [2] - 2:13, 127:9</p> <p>SOUTHERN [1] - 1:1</p> <p>Southern [2] - 7:3, 188:16</p> <p>Southwood [17] - 148:2, 148:11, 148:12, 148:13, 148:17, 149:9, 151:3, 151:6, 152:3, 152:12, 226:4, 226:19, 226:24, 227:8, 227:16, 228:24</p> <p>Southwood's [1] - 150:8</p>	<p>speaking [9] - 10:18, 38:21, 38:22, 38:23, 43:20, 90:21, 130:7, 130:8, 133:9</p> <p>special [1] - 211:14</p> <p>specific [22] - 8:22, 9:5, 9:6, 13:15, 37:17, 37:18, 39:16, 39:17, 39:21, 60:7, 74:13, 76:1, 76:3, 98:17, 107:17, 107:18, 112:8, 146:9, 196:19, 198:24, 200:5, 221:14</p> <p>specifically [6] - 21:24, 25:10, 57:19, 66:11, 74:21, 116:4</p> <p>specified [1] - 118:18</p> <p>specify [1] - 113:10</p> <p>speculating [1] - 27:6</p> <p>speculation [3] - 19:1, 19:9, 146:20</p> <p>speculative [1] - 185:13</p> <p>speed [1] - 119:19</p> <p>spend [2] - 54:10, 143:15</p> <p>spent [2] - 128:9, 134:7</p> <p>spoken [1] - 54:1</p> <p>spreading [1] - 24:10</p> <p>Squad [3] - 211:8, 211:10, 211:12</p> <p>Squads [1] - 211:18</p> <p>Square [2] - 6:5, 6:12</p> <p>staff [20] - 7:23, 27:20, 52:21, 83:16, 84:22, 85:1, 85:5, 91:11, 97:3, 97:6, 98:12, 99:3, 99:5, 147:1, 175:20, 175:23, 217:24, 240:4, 243:2</p> <p>Stafford [1] - 78:12</p> <p>stand [6] - 7:8, 7:10, 38:23, 40:23, 138:9, 138:21</p> <p>standard [1] - 29:24</p> <p>standing [3] - 42:19, 65:7, 136:24</p> <p>STANNER [1] - 5:10</p> <p>stared [1] - 17:9</p> <p>start [13] - 7:17, 56:15, 73:2, 115:4, 128:6, 139:2, 170:14, 182:22, 184:14, 210:4, 218:22</p> <p>started [12] - 12:10, 12:11, 22:4, 22:15, 25:10, 70:21, 84:4,</p>	<p>127:10, 145:19, 170:6, 195:25, 207:2</p> <p>starting [3] - 48:6, 166:3, 241:11</p> <p>starts [1] - 242:7</p> <p>state [12] - 18:7, 39:3, 39:5, 42:10, 104:20, 205:14, 207:15, 207:25, 208:1, 211:14, 218:6, 241:20</p> <p>statement [17] - 17:14, 51:10, 51:11, 98:14, 98:19, 188:4, 188:9, 188:11, 191:17, 203:5, 213:24, 225:16, 233:9, 234:13, 235:19, 238:15, 239:2</p> <p>statements [2] - 40:11, 186:8</p> <p>states [4] - 24:21, 207:12, 208:4, 244:2</p> <p>States [13] - 7:2, 22:3, 22:16, 106:5, 117:18, 120:21, 145:1, 171:11, 184:25, 196:19, 201:23, 201:25, 216:24</p> <p>STATES [2] - 1:1, 1:17</p> <p>status [1] - 129:4</p> <p>STATUS [1] - 1:17</p> <p>Status [1] - 7:2</p> <p>statute [2] - 198:4, 215:12</p> <p>statutory [4] - 117:7, 118:6, 118:10, 157:5</p> <p>stay [1] - 221:9</p> <p>stayed [2] - 204:24, 205:4</p> <p>steal [1] - 201:11</p> <p>stealing [1] - 191:2</p> <p>stenography [1] - 6:19</p> <p>step [3] - 31:10, 31:13, 67:22</p> <p>steps [2] - 169:24, 242:15</p> <p>STEVEN [1] - 4:17</p> <p>stick [1] - 206:15</p> <p>still [16] - 7:13, 25:25, 26:1, 29:2, 36:22, 107:24, 127:20, 134:22, 167:18, 189:25, 194:18, 225:3, 226:3, 231:19, 233:8, 239:17</p> <p>stipulation [1] - 108:25</p>	<p>stood [1] - 55:16</p> <p>stop [14] - 29:5, 29:7, 31:8, 64:9, 80:25, 95:25, 122:1, 141:15, 151:17, 156:11, 174:6, 204:15, 248:23, 248:24</p> <p>stopped [2] - 175:3, 176:3</p> <p>stopping [3] - 79:9, 104:11, 184:7</p> <p>stops [2] - 204:11</p> <p>stores [3] - 94:17, 95:6, 95:10</p> <p>story [3] - 236:11, 237:21, 238:4</p> <p>straight [3] - 57:4, 78:10, 241:2</p> <p>straightforward [2] - 172:23, 173:1</p> <p>strategic [1] - 211:5</p> <p>strategies [1] - 166:13</p> <p>stream [1] - 40:15</p> <p>Street [15] - 2:7, 2:10, 2:13, 3:5, 3:7, 3:10, 3:12, 4:6, 4:13, 4:15, 4:18, 5:5, 5:12, 6:6, 6:13</p> <p>strength [1] - 157:23</p> <p>stretch [1] - 130:4</p> <p>strictly [1] - 160:15</p> <p>strike [4] - 14:23, 52:23, 56:20, 165:12</p> <p>striking [1] - 52:16</p> <p>strong [2] - 206:11, 222:17</p> <p>struck [3] - 52:3, 52:4, 71:4</p> <p>struggling [1] - 96:24</p> <p>stuck [1] - 125:8</p> <p>studies [2] - 190:23, 197:18</p> <p>stuff [1] - 238:11</p> <p>style [1] - 221:1</p> <p>Subcommittee [1] - 187:13</p> <p>subject [9] - 13:1, 55:23, 74:5, 102:12, 123:4, 137:9, 176:5, 195:5, 233:13</p> <p>subjects [1] - 130:8</p> <p>submit [3] - 56:4, 92:2, 188:7</p> <p>submitted [6] - 91:25, 103:20, 112:21, 134:22, 217:17, 217:19</p> <p>subpoenas [1] - 137:17</p>	<p>Subsection [1] - 69:16</p> <p>subsequently [2] - 36:20, 46:1</p> <p>substance [10] - 47:8, 57:23, 158:22, 159:14, 160:14, 160:17, 196:19, 201:24, 202:8, 202:10</p> <p>Substances [15] - 60:8, 62:14, 62:23, 72:15, 115:22, 116:4, 116:25, 121:16, 144:9, 154:21, 171:14, 171:19, 203:14, 204:7, 234:4</p> <p>substances [56] - 9:13, 18:17, 29:6, 29:8, 47:19, 48:12, 48:17, 61:13, 69:9, 69:13, 69:15, 69:18, 78:23, 79:10, 80:21, 81:9, 81:13, 84:8, 89:15, 89:17, 104:15, 105:3, 118:17, 120:14, 121:9, 140:17, 140:22, 141:8, 141:13, 153:2, 158:24, 159:5, 159:8, 159:9, 160:11, 160:15, 160:21, 160:22, 165:1, 184:16, 190:17, 190:18, 190:22, 191:1, 196:17, 202:4, 203:11, 220:11, 220:25, 222:20, 234:11, 234:20, 235:4, 247:5, 247:18, 247:22</p> <p>substantial [2] - 134:4, 135:2</p> <p>substantive [1] - 196:13</p> <p>successfully [2] - 234:1, 234:23</p> <p>sufficient [1] - 129:12</p> <p>suggest [5] - 30:12, 52:17, 56:10, 120:15, 121:1</p> <p>suggested [1] - 129:23</p> <p>suggesting [2] - 27:24, 245:9</p> <p>suggestion [3] - 46:13, 114:6, 164:4</p> <p>Suite [9] - 2:4, 2:7,</p>
--	--	---	---	--

<p>2:10, 2:13, 2:16, 3:17, 4:6, 6:5, 6:12 summarized [1] - 219:6 summarizes [1] - 232:9 summary [1] - 245:11 Sunday [1] - 74:9 supervising [1] - 161:13 supervision [1] - 100:5 supervisor [1] - 91:10 supplied [4] - 217:1, 217:4, 228:9, 228:11 supplier [4] - 140:9, 140:17, 140:20, 140:21 supply [1] - 38:5 supplying [2] - 37:1, 235:18 support [3] - 53:7, 207:24 supposed [7] - 14:18, 14:19, 14:20, 18:17, 19:16, 139:14, 216:4 surely [1] - 238:13 surprised [2] - 130:14, 134:11 surprising [2] - 18:15, 122:17 surrender [2] - 236:22, 237:24 survey [1] - 190:23 suspect [3] - 87:20, 122:25, 194:16 suspected [4] - 104:15, 105:19, 106:1, 141:13 suspend [1] - 117:22 Suspension [51] - 28:11, 28:13, 28:14, 29:4, 29:13, 29:18, 29:20, 29:25, 30:9, 30:20, 37:4, 59:12, 59:13, 59:19, 59:23, 60:7, 61:1, 61:5, 61:11, 63:3, 63:22, 65:17, 66:3, 67:9, 73:14, 73:16, 77:3, 77:11, 77:17, 77:23, 78:4, 80:8, 81:19, 81:25, 82:8, 86:5, 89:4, 89:6, 89:8, 89:9, 89:13, 91:4, 91:22, 92:6, 94:11, 96:14, 115:17, 148:22, 149:2, 185:25, 206:3 suspension [4] -</p>	<p>28:24, 29:14, 37:4, 118:11 suspicion [1] - 13:16 suspicious [2] - 152:9, 178:8 Suspicious [27] - 18:16, 50:13, 53:22, 113:2, 173:24, 178:1, 178:14, 179:6, 179:13, 182:2, 182:12, 182:17, 182:19, 216:14, 230:22, 231:1, 231:6, 231:8, 240:8, 240:12, 246:16, 246:19, 246:23, 247:3, 247:4, 247:6, 247:8 suspicious [82] - 13:16, 14:17, 18:12, 36:24, 48:17, 49:1, 49:3, 51:5, 52:17, 52:24, 55:7, 57:2, 64:13, 64:16, 69:14, 81:9, 82:21, 89:21, 95:24, 102:17, 103:11, 103:14, 103:15, 103:19, 103:23, 103:25, 104:8, 104:9, 104:10, 105:3, 107:4, 107:15, 110:23, 111:10, 111:21, 112:1, 112:13, 112:19, 112:20, 112:23, 112:25, 114:11, 115:2, 116:4, 116:5, 116:25, 118:5, 118:7, 118:25, 119:1, 119:20, 140:4, 140:25, 145:6, 145:9, 145:12, 145:17, 145:20, 152:4, 156:4, 169:12, 172:11, 172:16, 172:20, 172:25, 179:9, 183:2, 183:24, 186:14, 186:18, 204:10, 215:2, 215:22, 216:12, 217:18, 217:19, 230:16, 235:18, 244:4, 244:11, 244:17, 247:14 sustain [23] - 12:15, 19:8, 19:10, 23:4, 34:10, 50:23, 51:16,</p>	<p>57:3, 57:5, 64:25, 100:2, 101:5, 102:8, 104:24, 146:8, 161:9, 169:21, 171:21, 195:3, 195:20, 196:9, 207:9, 209:4 Sustained [5] - 69:24, 70:7, 105:10, 185:15, 205:16 sustained [12] - 13:6, 27:5, 51:10, 57:21, 86:13, 87:3, 103:6, 104:24, 171:18, 173:18, 175:10, 183:20 sustaining [1] - 209:12 SUZANNE [1] - 4:15 sweat [1] - 128:10 Swedesboro [1] - 78:2 sweep [1] - 179:18 Switch [2] - 163:9, 163:11 sworn [1] - 238:15 Syracuse [2] - 142:6, 142:13 system [56] - 18:9, 18:11, 18:12, 18:20, 18:24, 19:4, 19:15, 19:18, 20:10, 38:18, 39:11, 39:23, 40:3, 40:7, 45:14, 45:16, 48:25, 63:14, 64:8, 64:12, 64:14, 64:15, 67:15, 103:16, 113:3, 145:19, 157:24, 174:5, 178:2, 178:6, 178:7, 178:24, 182:4, 182:5, 197:7, 200:11, 201:2, 201:9, 203:3, 203:10, 203:15, 203:16, 210:5, 210:8, 210:9, 210:11, 210:13, 210:15, 211:16, 231:16, 231:18, 240:17 System [12] - 53:23, 69:12, 178:2, 178:14, 179:6, 179:14, 182:12, 216:14, 230:22, 231:1, 231:7, 231:9 systemic [17] - 18:21, 19:21, 20:8, 39:10, 39:23, 62:1, 63:24, 64:14, 66:5, 67:11,</p>	<p>67:15, 82:1, 82:6, 88:20, 90:19, 90:25, 230:13 Systems [2] - 182:3, 182:19 systems [21] - 40:1, 40:2, 45:9, 45:14, 45:20, 51:6, 52:18, 52:22, 52:25, 54:23, 55:7, 57:2, 63:10, 63:13, 63:15, 64:5, 67:13, 67:16, 86:17, 178:12, 179:20</p> <p style="text-align: center;">T</p> <p>tablet [4] - 16:18, 24:16, 24:17, 24:18 tablets [6] - 17:25, 25:12, 71:24, 191:13, 228:12, 228:14 Tactical [4] - 211:8, 211:10, 211:12, 211:18 tail [1] - 165:17 talks [4] - 237:3, 237:5, 242:15, 245:17 Tampa [2] - 11:16, 15:22 target [1] - 39:8 task [2] - 131:4, 132:17 Task [7] - 211:13, 246:20, 246:23, 247:3, 247:4, 247:6, 247:9 tasks [1] - 180:6 TDS [1] - 211:10 tears [1] - 128:11 techniques [7] - 8:16, 42:4, 43:4, 165:24, 170:15, 174:11, 174:17 technological [1] - 158:12 TEMITOPE [1] - 4:8 ten [2] - 67:20, 129:21 Tenth [1] - 5:12 tenure [37] - 24:1, 28:24, 29:13, 29:25, 30:10, 30:19, 31:3, 31:18, 51:2, 54:18, 57:10, 57:14, 72:7, 113:20, 113:23, 114:19, 114:25, 154:15, 160:3, 167:20, 171:4, 172:21, 174:8,</p>	<p>175:17, 177:3, 177:15, 180:20, 181:3, 181:20, 183:1, 183:13, 186:1, 195:8, 199:3, 205:6, 240:16, 240:17 term [10] - 22:21, 23:25, 24:3, 24:4, 24:11, 24:13, 24:15, 28:11, 147:7, 148:24 termed [1] - 183:10 terminated [2] - 222:19, 223:6 terms [10] - 8:6, 18:19, 19:4, 33:5, 38:14, 134:24, 135:17, 159:12, 194:23, 212:6 terribly [1] - 27:16 Terrorism [1] - 187:13 testified [33] - 7:21, 38:17, 39:9, 43:24, 49:24, 53:25, 54:3, 54:13, 56:7, 56:9, 56:13, 56:22, 62:5, 62:7, 64:5, 67:12, 76:20, 77:1, 142:12, 146:1, 159:18, 160:4, 164:15, 166:14, 167:12, 187:14, 187:19, 189:7, 189:11, 209:2, 217:9, 238:9, 239:15 testifies [1] - 93:11 testify [24] - 42:25, 53:13, 70:21, 76:24, 86:20, 93:5, 93:15, 100:15, 120:21, 120:24, 128:2, 130:24, 167:2, 170:13, 186:25, 187:14, 189:7, 209:1, 213:18, 241:19, 245:18, 246:18, 246:23, 247:12 testifying [6] - 14:25, 15:4, 40:24, 98:8, 100:19, 113:25 testimonies [1] - 192:1 testimony [79] - 8:7, 11:19, 12:20, 26:7, 28:1, 38:15, 40:11, 40:18, 42:9, 49:22, 54:21, 55:4, 55:9, 56:19, 65:2, 73:22, 73:23, 74:9, 74:11,</p>
---	--	--	---	---

<p>75:1, 75:19, 75:24, 86:16, 97:4, 98:18, 100:5, 105:22, 122:13, 123:2, 123:3, 123:4, 123:16, 125:13, 126:8, 134:16, 135:4, 135:7, 135:10, 135:20, 165:12, 167:7, 167:12, 167:15, 171:18, 175:9, 184:15, 187:12, 187:24, 188:17, 189:3, 189:5, 189:15, 190:5, 191:14, 193:18, 195:14, 195:17, 213:19, 216:1, 216:6, 218:5, 218:7, 225:21, 225:23, 230:12, 230:14, 230:24, 238:15, 238:17, 238:24, 239:1, 239:13, 242:8, 243:5, 246:6, 246:14, 246:15, 248:5</p> <p>tether [1] - 166:24</p> <p>Texas [4] - 46:10, 47:4, 47:6, 12:12</p> <p>text [1] - 226:16</p> <p>THE [322] - 1:1, 1:1, 1:4, 1:17, 7:6, 7:9, 7:12, 7:13, 7:14, 8:4, 8:19, 8:21, 9:1, 10:5, 11:13, 11:17, 12:1, 12:15, 12:22, 13:6, 14:13, 14:15, 15:5, 17:22, 17:24, 19:8, 20:3, 20:5, 23:1, 23:4, 26:5, 26:14, 27:5, 27:15, 27:17, 28:3, 28:6, 32:2, 33:12, 33:16, 33:25, 34:6, 34:17, 34:20, 35:3, 35:7, 35:10, 35:13, 35:23, 35:25, 36:1, 36:3, 36:5, 36:7, 36:9, 38:8, 38:10, 38:12, 38:25, 39:22, 39:25, 40:10, 41:3, 41:18, 41:24, 42:6, 42:12, 42:21, 43:5, 43:11, 46:17, 46:25, 50:1, 50:20, 50:23, 51:16, 51:19, 51:22, 52:8, 53:4, 53:20, 55:11, 55:18, 55:22, 56:15, 56:21, 56:25, 57:21, 59:9,</p>	<p>62:9, 62:17, 62:18, 62:25, 63:7, 63:9, 64:10, 64:12, 64:25, 65:6, 65:9, 65:12, 66:9, 66:19, 66:23, 67:5, 67:18, 67:20, 67:23, 68:2, 68:6, 69:24, 70:7, 70:13, 70:17, 71:6, 71:16, 71:18, 71:22, 72:4, 74:6, 74:18, 75:9, 76:5, 76:15, 76:23, 79:4, 79:23, 81:17, 81:18, 82:3, 82:4, 83:6, 83:11, 84:11, 84:13, 84:15, 85:12, 86:8, 86:23, 87:6, 87:12, 88:1, 88:13, 88:18, 90:9, 90:10, 90:23, 90:24, 92:19, 92:20, 93:7, 93:12, 93:17, 93:19, 93:20, 94:4, 94:5, 94:22, 95:2, 95:5, 95:19, 95:20, 98:21, 99:25, 100:1, 100:9, 100:18, 101:5, 101:15, 102:8, 102:21, 102:23, 103:1, 103:3, 103:7, 104:24, 105:10, 105:24, 106:9, 106:24, 107:1, 107:8, 107:10, 107:13, 107:16, 107:19, 108:22, 109:11, 109:22, 109:23, 111:1, 111:2, 111:14, 111:17, 112:12, 112:18, 113:13, 113:16, 114:17, 114:19, 115:7, 120:25, 121:4, 121:22, 121:23, 122:1, 122:4, 122:7, 124:2, 124:14, 124:18, 125:17, 127:7, 128:13, 128:24, 131:18, 131:23, 132:21, 133:3, 133:9, 133:22, 134:6, 135:25, 136:9, 136:19, 137:22, 138:4, 138:11, 138:23, 143:8, 143:17, 145:7, 145:8, 146:8, 146:22, 146:24, 147:10, 147:14,</p>	<p>150:14, 150:16, 150:25, 154:4, 154:9, 155:9, 155:13, 155:25, 159:24, 161:9, 162:11, 163:3, 163:5, 164:8, 164:17, 165:15, 165:21, 167:1, 167:14, 169:21, 170:17, 170:18, 170:19, 170:20, 170:25, 171:21, 173:18, 174:15, 174:22, 175:10, 176:7, 178:19, 178:23, 183:20, 184:4, 184:6, 184:10, 185:15, 188:2, 188:20, 189:20, 189:23, 190:2, 191:21, 191:22, 192:6, 193:8, 193:16, 193:19, 193:23, 194:3, 194:5, 195:3, 195:20, 196:9, 203:24, 204:1, 205:16, 206:21, 206:24, 207:7, 208:18, 209:4, 209:11, 209:16, 209:21, 210:1, 210:2, 214:15, 218:8, 219:2, 223:14, 224:3, 224:7, 224:21, 225:11, 225:13, 229:20, 238:19, 241:23, 248:23, 248:25, 249:3, 249:4</p> <p>themselves [1] - 33:10</p> <p>theory [1] - 88:19</p> <p>therefore [3] - 64:14, 67:15, 145:17</p> <p>they've [10] - 52:5, 116:12, 127:1, 127:23, 128:3, 129:20, 137:8, 159:17, 179:10</p> <p>thick [1] - 240:23</p> <p>third [13] - 16:4, 52:12, 118:2, 119:25, 120:1, 123:4, 163:14, 163:15, 165:4, 225:4, 232:12, 236:2, 237:2</p> <p>Thomas [2] - 2:12, 55:24</p> <p>thoughtful [1] - 132:3</p>	<p>thousands [5] - 70:24, 71:19, 71:24, 185:8, 185:24</p> <p>threaded [1] - 138:18</p> <p>threat [11] - 30:1, 30:7, 30:12, 30:17, 30:25, 61:14, 61:16, 61:21, 81:14, 89:11, 234:2</p> <p>Three [1] - 6:5</p> <p>three [34] - 6:12, 24:5, 31:3, 45:13, 63:15, 63:18, 63:19, 69:14, 126:22, 130:6, 130:7, 132:7, 132:14, 132:21, 147:3, 147:11, 158:3, 170:5, 176:17, 176:23, 177:5, 181:9, 202:22, 208:11, 232:5, 232:14, 232:19, 232:21, 232:23, 235:11, 236:17, 245:15, 247:15</p> <p>threshold [4] - 111:3, 111:19, 111:23, 247:14</p> <p>thresholds [4] - 183:2, 183:12, 183:17, 183:23</p> <p>throughout [7] - 22:15, 25:21, 67:16, 125:2, 204:23, 212:23</p> <p>throw [2] - 132:13, 157:24</p> <p>Thursday [1] - 138:7</p> <p>time-out [1] - 67:18</p> <p>timing [2] - 34:4, 159:13</p> <p>TIMOTHY [1] - 5:9</p> <p>today [6] - 7:18, 42:16, 122:12, 122:22, 122:23, 216:7</p> <p>together [1] - 54:2</p> <p>token [1] - 199:15</p> <p>took [12] - 34:6, 39:20, 40:25, 43:21, 64:13, 66:14, 98:25, 181:19, 182:21, 204:19, 227:8, 245:7</p> <p>tool [1] - 168:2</p> <p>tools [6] - 165:10, 165:24, 166:3, 166:10, 234:1, 234:3</p> <p>top [6] - 16:2, 47:14, 60:10, 60:12, 89:15, 222:11</p> <p>topic [4] - 42:17,</p>	<p>184:3, 196:13, 248:21</p> <p>topics [3] - 135:22, 184:12, 215:4</p> <p>total [9] - 61:19, 67:15, 123:2, 124:1, 124:9, 124:13, 196:18, 204:21, 242:5</p> <p>totally [2] - 128:16, 133:21</p> <p>touch [1] - 215:4</p> <p>touched [1] - 210:18</p> <p>Touhy [3] - 42:15, 42:20, 43:8</p> <p>tour [1] - 156:12</p> <p>toward [1] - 133:18</p> <p>Tower [2] - 3:4, 4:18</p> <p>town [1] - 136:21</p> <p>Track [3] - 73:25, 75:4, 76:19</p> <p>track [2] - 44:18, 119:21</p> <p>traffic [1] - 20:25</p> <p>trained [1] - 139:13</p> <p>transactions [12] - 12:10, 109:4, 110:1, 110:3, 110:23, 111:3, 111:8, 111:18, 111:23, 157:16, 157:17</p> <p>transcended [1] - 88:20</p> <p>transcript [4] - 6:19, 74:21, 87:8, 250:4</p> <p>transition [1] - 193:13</p> <p>transitioned [1] - 196:4</p> <p>transmitted [1] - 74:24</p> <p>transparency [1] - 153:22</p> <p>transpired [1] - 174:13</p> <p>transported [1] - 24:21</p> <p>tread [1] - 20:14</p> <p>treated [1] - 123:12</p> <p>treaties [1] - 197:6</p> <p>treating [1] - 184:25</p> <p>Trial [1] - 249:6</p> <p>trial [23] - 34:4, 73:21, 122:12, 122:22, 123:9, 125:2, 125:23, 126:16, 126:22, 127:3, 127:6, 127:11, 127:17, 128:20, 130:4, 130:16, 131:10, 132:15, 134:13, 135:10, 137:10, 195:16</p>
--	---	--	--	---

TRIAL ^[1] - 1:16 trials ^[2] - 122:19, 122:20 tried ^[2] - 55:3, 132:4 trimming ^[1] - 123:20 trinity ^[2] - 26:1 trip ^[1] - 204:15 trouble ^[2] - 138:19, 193:23 true ^[10] - 50:14, 50:18, 52:6, 52:7, 54:25, 160:5, 191:17, 228:16, 231:5, 234:15 True ^[4] - 210:22, 212:12, 212:21, 230:7 truth ^[1] - 223:22 truthful ^[1] - 235:7 truthfully ^[1] - 213:18 try ^[16] - 33:24, 34:16, 52:12, 52:15, 53:16, 96:23, 100:14, 151:14, 158:11, 175:12, 176:7, 192:8, 213:25, 214:23, 221:5, 231:5 Try ^[1] - 92:22 trying ^[18] - 19:25, 27:24, 27:25, 31:7, 34:3, 38:6, 86:10, 106:23, 142:12, 142:14, 193:5, 194:19, 200:13, 206:6, 213:18, 229:24, 240:13 Turn ^[1] - 86:1 turn ^[53] - 15:24, 32:13, 36:17, 44:5, 45:24, 47:14, 47:25, 48:20, 57:23, 57:24, 60:10, 64:17, 68:18, 68:21, 72:20, 72:24, 73:10, 77:6, 77:19, 78:6, 79:17, 80:14, 83:23, 84:17, 85:9, 85:18, 85:21, 85:24, 96:5, 97:25, 115:14, 116:7, 116:15, 116:18, 117:6, 118:2, 119:1, 119:25, 121:25, 139:5, 140:2, 141:22, 144:11, 151:11, 152:15, 155:15, 156:6, 156:13, 171:25, 186:23, 190:6, 196:14 turned ^[2] - 56:12,	84:5 turning ^[4] - 145:13, 154:22, 172:1, 176:12 Twelfth ^[3] - 4:13, 4:15, 5:5 twice ^[2] - 44:17, 136:12 two ^[26] - 14:11, 14:16, 33:6, 38:13, 74:7, 75:23, 84:1, 84:11, 90:14, 93:17, 95:8, 104:4, 121:8, 125:12, 126:2, 130:17, 132:15, 133:7, 133:20, 136:20, 193:1, 197:21, 208:11, 226:7, 239:18, 245:14 two-hour ^[1] - 126:2 tying ^[1] - 75:19 type ^[8] - 17:8, 37:22, 109:2, 109:13, 157:21, 164:24, 181:9, 191:22 types ^[3] - 25:7, 95:16, 165:23 typically ^[4] - 85:1, 139:20, 177:10, 191:3	40:10, 53:15, 56:25, 57:7, 63:12, 107:2, 107:13, 144:9 Understood ^[1] - 87:9 undertake ^[2] - 96:21, 217:21 undertook ^[1] - 9:11 unfair ^[1] - 75:20 unforgettable ^[1] - 128:17 unintelligible ^[1] - 49:11 unit ^[5] - 16:16, 16:19, 118:18, 198:8 United ^[13] - 7:2, 22:2, 22:16, 106:4, 117:18, 120:20, 144:25, 171:11, 184:25, 196:19, 201:23, 201:25, 216:24 UNITED ^[2] - 1:1, 1:17 units ^[6] - 16:15, 60:21, 70:25, 196:25, 229:10, 239:18 universe ^[1] - 184:22 unlawfully ^[1] - 185:10 unless ^[3] - 128:23, 214:1, 235:17 unlimited ^[2] - 129:16, 130:11 unprecedented ^[1] - 126:9 unusual ^[1] - 16:22 unworkable ^[1] - 133:21 Up ^[1] - 240:16 up ^[68] - 7:20, 8:22, 14:12, 14:14, 16:1, 18:10, 18:13, 18:17, 18:22, 18:23, 21:5, 21:16, 24:6, 24:9, 25:2, 29:23, 30:22, 34:6, 34:12, 40:5, 45:3, 50:24, 55:16, 59:25, 61:15, 65:2, 65:7, 71:20, 72:19, 85:10, 89:10, 107:24, 124:14, 127:8, 133:1, 145:20, 149:5, 153:7, 155:21, 158:13, 168:12, 168:13, 170:8, 179:20, 190:9, 190:12, 193:21, 198:1, 198:3, 199:9, 204:14, 212:14,	213:4, 219:22, 225:4, 226:9, 226:14, 233:16, 233:22, 235:24, 239:11, 240:24, 244:3, 244:10, 244:17, 245:22, 248:13 upset ^[5] - 17:16, 17:17, 17:20, 225:21 upstream ^[1] - 191:10 useful ^[2] - 111:11, 162:22 users ^[2] - 195:24, 195:25 uses ^[2] - 117:20, 244:3	191:7, 234:11, 234:20 view ^[2] - 37:24, 100:23 viewing ^[1] - 134:5 views ^[2] - 206:11, 211:21 violated ^[3] - 34:9, 60:8, 89:23 violation ^[2] - 29:17, 141:10 violations ^[8] - 28:17, 31:11, 39:15, 44:3, 61:25, 72:1, 149:4 Virginia ^[10] - 4:18, 7:3, 7:4, 139:13, 220:4, 223:13, 226:9, 229:3, 231:22, 235:23 VIRGINIA ^[2] - 1:1, 1:18 vision ^[2] - 129:11, 132:1 visit ^[3] - 24:5, 24:24, 181:11 visits ^[2] - 181:10, 181:19 volume ^[10] - 16:22, 17:1, 134:11, 167:24, 169:24, 170:10, 190:16, 190:18, 234:9, 234:18 VOLUME ^[1] - 1:16 volumes ^[11] - 9:13, 13:14, 16:21, 79:9, 95:11, 167:25, 170:1, 170:11, 217:7, 217:8, 227:5 voluminous ^[1] - 108:23 voluntarily ^[1] - 141:12 voluntary ^[2] - 236:22, 237:24 vs ^[2] - 188:14, 250:6
V				
vague ^[9] - 14:10, 27:23, 62:16, 69:23, 110:25, 164:6, 185:11, 191:19, 191:20 vagueness ^[1] - 63:6 valid ^[2] - 156:3, 186:7 validate ^[2] - 157:15, 157:25 validated ^[3] - 157:15, 233:2, 235:12 validation ^[5] - 157:19, 158:3, 197:18, 197:25, 199:19 value ^[1] - 111:18 variation ^[1] - 247:12 various ^[3] - 26:8, 152:17, 161:25 vast ^[2] - 30:15, 121:8 vault ^[1] - 179:22 vehicle ^[3] - 149:24, 160:16, 183:16 vein ^[2] - 118:20, 118:22 Ventura ^[1] - 3:18 venues ^[1] - 25:22 verbatim ^[1] - 107:18 Verification ^[1] - 242:14 verified ^[2] - 242:23, 243:6 verify ^[2] - 242:15, 242:19 version ^[4] - 143:12, 150:9, 150:10, 150:11 versus ^[2] - 160:21, 203:7 via ^[5] - 190:25, 191:5,				
U				
U.S.C ^[1] - 196:20 ultimately ^[1] - 79:14 UN ^[2] - 197:6, 198:8 un-blacked ^[2] - 229:6, 229:7 un-ring ^[1] - 175:12 unable ^[3] - 74:13, 112:7, 236:4 unanimous ^[1] - 55:12 unclear ^[1] - 70:11 under ^[32] - 7:13, 30:3, 34:25, 42:24, 49:22, 49:24, 55:14, 57:16, 115:22, 116:3, 116:24, 118:22, 122:21, 132:8, 140:15, 144:9, 151:22, 155:21, 164:15, 174:7, 174:16, 174:23, 175:2, 188:8, 188:11, 190:6, 197:5, 197:6, 197:10, 201:5, 238:9 Under ^[1] - 246:18 understood ^[8] -				
W				
wait ^[2] - 41:18, 50:20 WAKEFIELD ^[1] - 5:13 walk ^[4] - 22:11, 75:20, 178:11, 232:2 Walker ^[2] - 237:8, 248:6 wants ^[1] - 53:12 war ^[5] - 205:23, 207:2, 208:23, 209:2 warehouse ^[1] - 179:25				

<p>warned [2] - 61:8, 82:11</p> <p>warrant [3] - 86:14, 87:2, 118:10</p> <p>Washington [8] - 2:11, 4:7, 4:14, 4:16, 5:5, 5:12, 208:16, 209:9</p> <p>waste [1] - 85:16</p> <p>watch [1] - 178:7</p> <p>watching [2] - 126:11, 128:21</p> <p>water [2] - 35:22, 36:4</p> <p>wear [1] - 138:16</p> <p>wearing [1] - 138:15</p> <p>WEBB [1] - 3:11</p> <p>Webb [1] - 3:12</p> <p>website [7] - 150:6, 150:9, 150:11, 153:20, 153:21, 155:6</p> <p>week [9] - 127:16, 127:20, 129:10, 133:23, 133:24, 134:7, 136:7, 138:6</p> <p>weekly [1] - 104:3</p> <p>weeks [16] - 103:21, 104:4, 110:11, 129:5, 130:16, 130:17, 131:12, 131:19, 131:22, 131:24, 132:15, 133:20, 137:7, 177:13, 178:13, 220:14</p> <p>weight [2] - 11:22, 88:24</p> <p>welcome [1] - 124:21</p> <p>WEST [2] - 1:1, 1:18</p> <p>West [8] - 7:3, 7:4, 220:4, 223:13, 226:9, 229:2, 231:22, 235:23</p> <p>WESTFALL [21] - 8:3, 8:6, 8:12, 8:20, 8:25, 42:2, 42:24, 43:6, 49:10, 49:13, 49:23, 50:4, 93:21, 94:2, 106:4, 113:24, 120:20, 165:22, 170:12, 170:24, 174:9</p> <p>Westfall [5] - 8:10, 8:22, 42:1, 42:22, 165:21</p> <p>whereas [1] - 47:16</p> <p>white [1] - 158:12</p> <p>whole [10] - 24:23, 33:13, 35:3, 35:14, 120:6, 127:5, 149:3,</p>	<p>151:6, 181:7, 197:13</p> <p>wholesale [2] - 212:21, 214:13</p> <p>wholesalers [1] - 9:6</p> <p>wicht [1] - 33:16</p> <p>WICHT [71] - 4:12, 19:2, 22:20, 26:6, 26:12, 27:3, 33:17, 42:14, 55:13, 56:17, 64:18, 64:21, 73:4, 73:6, 73:19, 74:19, 76:7, 76:18, 78:24, 79:19, 79:24, 81:15, 82:2, 83:2, 86:10, 86:25, 87:9, 87:23, 88:14, 90:8, 90:20, 93:9, 94:21, 95:18, 98:3, 103:2, 104:20, 105:8, 106:25, 108:5, 108:9, 108:12, 109:20, 110:13, 110:25, 116:11, 120:17, 121:21, 137:1, 142:11, 142:24, 143:3, 143:9, 146:3, 146:5, 147:6, 150:18, 155:23, 161:5, 161:24, 162:24, 164:10, 171:17, 173:17, 185:11, 188:3, 189:21, 194:25, 206:8, 206:22, 207:4</p> <p>Wicht [17] - 42:13, 42:23, 55:11, 74:18, 76:5, 86:9, 86:24, 87:14, 87:18, 88:13, 103:1, 106:24, 136:24, 150:17, 164:9, 189:20, 206:21</p> <p>Wicht's [1] - 34:11</p> <p>wide [1] - 121:6</p> <p>Williams [2] - 4:13, 5:4</p> <p>willing [2] - 34:18, 131:23</p> <p>window [2] - 179:6, 216:18</p> <p>winnow [2] - 129:17, 130:12</p> <p>winnowing [4] - 130:5, 131:4, 132:18, 133:17</p> <p>Wise [7] - 225:18, 225:24, 226:10, 226:12, 226:24, 227:3, 228:11</p> <p>wish [3] - 44:20,</p>	<p>56:11, 120:19</p> <p>withdraw [1] - 135:13</p> <p>witness [63] - 7:8, 7:10, 22:21, 27:4, 34:8, 38:7, 38:15, 38:23, 40:19, 40:24, 53:2, 53:5, 53:11, 53:25, 54:9, 54:12, 55:5, 55:6, 55:10, 56:6, 62:4, 64:3, 64:19, 66:13, 73:20, 76:10, 86:16, 87:22, 93:11, 98:5, 98:8, 100:19, 102:3, 105:22, 112:7, 122:19, 124:5, 132:18, 135:3, 138:9, 138:21, 142:12, 142:15, 142:16, 143:11, 143:16, 155:11, 161:6, 165:19, 166:21, 183:18, 188:4, 188:23, 194:8, 206:8, 206:11, 207:6, 209:20, 223:20, 229:17, 229:24, 238:17, 241:19</p> <p>WITNESS [56] - 7:12, 7:14, 8:4, 14:15, 17:24, 20:5, 28:6, 35:25, 36:3, 36:7, 39:25, 46:17, 62:18, 63:9, 64:12, 66:9, 66:23, 67:23, 71:18, 71:22, 81:18, 82:4, 83:11, 84:13, 90:10, 90:24, 92:20, 93:17, 93:20, 94:4, 95:5, 95:20, 99:25, 107:10, 107:16, 109:23, 111:2, 111:17, 112:18, 114:19, 121:4, 121:23, 138:23, 145:8, 146:24, 147:14, 163:5, 170:17, 170:19, 170:25, 174:22, 178:23, 191:22, 204:1, 210:2, 249:3</p> <p>witness's [5] - 65:2, 193:18, 208:20, 218:5, 218:6</p> <p>witnesses [35] - 54:22, 123:13, 123:15, 123:19, 123:21, 123:23, 123:24, 124:7,</p>	<p>124:10, 124:22, 124:24, 125:8, 125:21, 126:5, 127:15, 127:20, 127:21, 127:24, 129:14, 129:17, 130:17, 130:23, 130:24, 131:10, 131:12, 131:13, 132:13, 133:16, 133:20, 135:17, 135:19, 135:24, 137:15, 242:5</p> <p>WOELFEL [1] - 3:9</p> <p>Woelfel [2] - 3:9</p> <p>word [2] - 76:6, 245:13</p> <p>words [2] - 18:7, 129:16</p> <p>workable [1] - 130:19</p> <p>works [6] - 134:9, 178:6, 196:17, 202:24, 204:5, 210:9</p> <p>world [2] - 127:12, 228:19</p> <p>worst [2] - 44:20, 212:3</p> <p>worth [1] - 127:17</p> <p>wrap [1] - 204:14</p> <p>Wright [1] - 237:18</p> <p>write [2] - 22:12, 202:19</p> <p>writing [3] - 120:12, 219:23, 221:23</p> <p>written [7] - 10:12, 58:10, 128:15, 180:14, 202:9, 202:11, 220:2</p> <p>wrote [1] - 219:25</p> <p>WU [1] - 5:10</p> <p>WV [6] - 2:8, 3:10, 3:13, 4:19, 5:15, 6:9</p>	<p>20:13, 98:15, 102:12, 102:17, 107:21, 112:6, 122:11, 122:12, 152:16, 156:12</p> <p>yield [1] - 173:16</p> <p>York [3] - 3:5, 142:6, 188:16</p> <p>young [1] - 190:21</p> <p>yourself [2] - 92:15, 231:1</p>
Z				
<p>zero [1] - 210:25</p>				
Y				
<p>year [10] - 9:7, 9:25, 31:23, 35:19, 36:12, 181:15, 191:13, 199:9, 208:11, 208:12</p> <p>years [15] - 166:12, 176:17, 176:18, 176:23, 177:5, 202:22, 204:22, 205:5, 208:11, 211:24, 215:16, 215:19, 240:5, 246:11</p> <p>yesterday [14] - 7:16, 7:22, 11:1, 11:19,</p>				